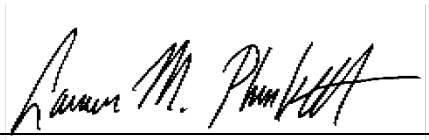
EXHIBIT C28

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION ***THIS DOCUMENT RELATES TO ALL CASES***	**MDL NO. 16-2738 (FLW) (LHG)**

RULE 26 EXPERT REPORT OF LAURA M. PLUNKETT, PH.D., DABT

Date: November 16, 2018



Laura M. Plunkett, Ph.D., DABT

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I. Training and Qualifications

1. I am a pharmacologist, toxicologist, United States Food and Drug Administration (FDA) regulatory specialist and principal of a consulting company known as Integrative Biostrategies, LLC. Integrative Biostrategies, based in Houston, Texas, is a consulting firm that works at the interface of biological science, regulatory affairs and business decisions to provide its clients with science-based solutions to issues associated with product development and stewardship. Before joining Integrative Biostrategies in 2001, I was head of the consulting firm known as Plunkett & Associates. Attached as Appendix A is a copy of my curriculum vitae.

2. I am board-certified as a Diplomate of the American Board of Toxicology. I am a member of several professional organizations and have authored or co-authored numerous scientific publications. I have over twenty years of experience in the areas of pharmacology and toxicology and have worked in both government and academic research. I have taught pharmacology and toxicology at the undergraduate and postgraduate levels.

3. I received a B.S. degree in 1980 from the University of Georgia and a Ph.D. in pharmacology from the University of Georgia, College of Pharmacy in 1984. My doctoral research was focused on the area of cardiovascular pharmacology, and specifically dealt with delineating neurochemical mechanisms responsible for the cardiac toxicity of digitalis glycosides. My training required my understanding of the mechanisms of action and basic pharmacology of drugs from all classes.

4. From June 1984 through August 1986, I was a Pharmacology Research Associate Training (PRAT) fellow at the National Institute of General Medical Sciences, Bethesda, Maryland. I worked in a neuroscience laboratory of the National Institute of Mental Health. My research focused on the role of various brain neurochemical systems involved in the control of autonomic nervous system and cardiovascular function.

5. From September 1986 to June 1989, I was an Assistant Professor of Pharmacology and Toxicology in the medical school at the University of Arkansas for Medical Sciences, Little Rock, Arkansas, where I performed basic research in the areas of neuropharmacology and

toxicology as well as cardiovascular pharmacology and toxicology. I taught courses for both medical students and graduate students in pharmacology and toxicology as well as the neurosciences. As a pharmacologist, my work was directed towards understanding the biologic mechanisms of drug actions.

6. From December 1989 to August 1997, I worked for ENVIRON Corporation, first in the Arlington, Virginia office and then in the Houston, Texas office. I worked specifically within the health sciences group and most of my projects dealt with issues surrounding products or processes regulated by the FDA. During my consulting career (ENVIRON, Plunkett & Associates, and Integrative Biostrategies), I have worked on a variety of projects dealing with the regulation of products by the FDA, including human drugs (both prescription and over-the-counter drugs), veterinary drugs, biologics, medical devices, cosmetics, consumer products, dietary supplements and foods. I have advised my clients on regulatory issues and strategies for their products, designed preclinical and clinical studies for both efficacy and safety, advised clients on issues related to statements regarding efficacy and warnings for their products based on the current labeling regulations, and generally acted as a regulatory affairs staff for small companies in early stages of product development. Among the clients that I have consulted with have been cosmetic ingredient manufacturers and manufacturers of finished cosmetic products, both large and small companies. A tool and generally accepted methodology common to all my work as a consultant would be risk assessment, including many projects where risks related to exposure to chemicals in consumer products were at issue. Also, as part of my risk assessment work, I commonly review and rely on epidemiology data, as well as animal and *in vitro* data in order to assess risks to human health.

7. With respect to my experience that is directly relevant to the issues in this case, I have done a great deal of work on projects related to regulation of cosmetics and cosmetic ingredients. As part of my regulatory practice as a consultant over more than 25 years, I have consulted with cosmetic ingredient manufacturers and manufacturers of cosmetic products on issues related to ingredient safety, product safety, labeling claims, and general regulatory compliance issues which include US regulations and regulations in other countries. These projects have been for companies of different sophistication in terms of their knowledge of cosmetic regulatory compliance. In some cases, I have worked with large companies and provided advice

on the safety of ingredients used to manufacture cosmetic products. In other cases, I have given advice to the company as part of an initial commercialization process, where the client was trying to decide how to market their product, *e.g.*, as a cosmetic or a drug, as well as to determine if their product was safe for human exposure. Prior to this litigation, I have worked on the safety of talc itself. In the 1990's, I consulted with companies making condoms, which are classified as medical devices,[1] and provided scientific advice on the safety of talcum powder that was used on the surfaces of the devices as a dry lubricant. This work included my assessment of the scientific literature, including epidemiology, animal and invitro studies that discussed potential adverse health effects linked to talc exposure, including both local tissue toxicity and systemic toxicity.

8. Related to the issue of cosmetic ingredient safety is the issue of determining if that ingredient is "generally-recognized-as-safe", or "GRAS". In many of my projects, the issue of whether a consumer product ingredient is GRAS is critical to determining what type of toxicity testing is needed to establish that a product or an ingredient is safe for human use. Like the reviews performed on cosmetic ingredients by members of panels such as the Cosmetic Ingredient Review (CIR) panel (the role of the CIR process and its panel is discussed in more detail below), GRAS reviews that I have performed involved consideration of animal and human toxicity data, cellular and mechanistic data, human product experience reports, and the type and level of exposure that may occur when humans are exposed to the ingredient or product.

9. As a pharmacologist and board-certified toxicologist, much of my consulting work has related to understanding and explaining the mechanisms of action of chemicals of all types, as well as the toxic effects of these chemicals. I have expertise in pharmacokinetics, where I have designed clinical trials and analyzed pharmacokinetic data. I have taught pharmacology to medical students and graduate students. I have lectured to graduate students, law students and pharmacy students on FDA regulations as they apply to all types of FDA-regulated products, including cosmetics. Throughout my career, I have published dozens of peer-reviewed articles, which are listed in my curriculum vitae (Appendix A). I have authored a book chapter on FDA pharmacovigilance practices. I have served as a peer-reviewer for medical journals in my capacity as a pharmacologist and toxicologist. In litigation, I have provided expert testimony and been

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=HIS

qualified by both state and federal courts in the areas of pharmacology, pharmacokinetics, toxicology, risk assessment and FDA regulations. A list of my previous testimony for the past five years is included as Appendix B.

II. Information Reviewed and Methodology Employed

10. In the current case, I have been asked to provide opinions related to the human health hazards posed by exposure to talcum powder products and how those hazards relate to the regulatory requirements for marketing cosmetic ingredients and cosmetic products in the United States. This report is the third report I have prepared in the nationwide talc litigation. I am prepared to provide testimony on many of the topics addressed in my two earlier reports dated October 5, 2016 and August 29, 2018 as well as opinions contained in testimony during hearings, depositions, and trials. This new report contains discussion of additional documents, scientific literature, reports, and deposition testimony that has become available since preparing my original report in October 2016 and even my supplemental report in August 2018. To provide a general summary, the relevant materials I've reviewed during the course of continuing work in this litigation include the following:

a) scientific literature relating to the biological effects and toxic effects of talc and other constituents that are present in talc body powders;

b) the Food, Drug and Cosmetic Act (FDCA) and regulations of the U.S. Food and Drug Administration (FDA) relating to the development and marketing of cosmetic ingredients and finished cosmetic products;

c) publicly available information on safety assessments of talc and products containing talc; and

d) documents produced during the litigation that are, for example, internal company documents, depositions of company employees, reports of other experts in the litigation, or documents found on public sites.

It should be noted that most of the sources listed above are ones commonly used in my work as a pharmacologist, toxicologist, risk assessor, and United States Food and Drug Administration (FDA) regulatory specialist, including internal company documents that often outline what was known by a manufacturer concerning their product as well as outlining company

policies that relate to marketing of cosmetic ingredients and cosmetic finished products in the United States. Additionally, it is important to point out that I have had access to a large database of internal company documents, documents produced as part of the discovery process in the litigation, and that I have performed my own searches of this database as part of my work on the case. In other instances, I have directed others to perform searches on my behalf. Finally, the manufacturers that are relevant to my opinions include Luzenac, a talc ingredient manufacturer that is a part of the company known today as Imerys,[2] and Johnson & Johnson, the manufacturer of finished talc body powder products, *i.e.*, Johnson's Baby Powder™. Shower to Shower™ and Shimmer™. The other group that is relevant to my opinions in this case is the trade organization for the cosmetics industry known as the Personal Care Products Council (PCPC), a group that was formerly known as the Cosmetic, Toiletry and Fragrance Association (CTFA).

11. With respect to the methodology employed in forming my opinions for this report and my earlier reports, I used standard and generally accepted methods that apply in all my work as a pharmacologist and toxicologist that is related to assessing the safety of products, both litigation and non-litigation projects. The tool I use for safety assessment is a method known as human health risk assessment. Toxicologists routinely assess risks to human health related to exposure to chemicals in the everyday environment using the risk assessment process. In fact, toxicology is the scientific core of risk assessment. Risk assessment is a methodology that has been used for decades by a wide variety of governmental bodies to evaluate the safety of chemicals encountered in the everyday environment and to identify the potential adverse health effects from such chemical exposures. In 1983, the National Research Council (NRC) detailed the steps for risk assessment and described the methodology that is in use today as four basic steps: hazard identification, dose-response assessment, exposure analysis, and characterization of risks (NRC, 1983). As a result, risk assessment is a standard tool used by toxicologists when they are trying to determine if exposure to a chemical(s), or a product, poses a risk to human health. Therefore, as with any project I perform involving safety assessment, I use risk assessment as a tool. The methodology of human health risk assessment is a tool described in the *Reference Manual on*

[2] Since 1989, Imerys Talc America, Inc. ("Imerys") or one of its predecessor companies have supplied talc to Johnson & Johnson for its talcum powder products. These predecessor companies include Cyprus Talc Corporation, Luzenac America, Inc., and Rio Tinto Group. Throughout this report, these entities should be considered synonymous with Imerys

Scientific Evidence, Third Edition (NRC, 2011) which is a resource developed for courts when evaluating methodology used by scientists in litigation projects.

12. The first step in any risk assessment is the one I employed here, *i.e.*, identifying, collecting, reviewing, assessing, and evaluating data from the peer-reviewed scientific literature. This literature is used as the basis of the information employed in the first two steps of the risk assessment, *i.e.*, hazard identification and dose-response assessment. In this case, that literature review involved extensive searching of the published literature that described the effects of talc and talc-based products on some aspect of human health. I used available databases to systematically search the published literature for all relevant literature. The papers I identified described the effects of talc on living organisms, tissues and cells. Some of the resources I identified were textbooks and government documents that provided overviews of the human health risks associated with talc exposure. Also included in my searches were other compounds or chemicals that are constituent parts of talc-based body powders. I had to analyze and evaluate the relevant information. For this process I employed another tool and generally accepted methodology known as a "weight-of-the-evidence" assessment. A weight-of-the-evidence assessment involves evaluating individual studies and determining what the studies describe, when considered as a whole. Therefore, weight-of-the-evidence methods were critical to defining the literature that identified the hazards of talc exposure as well as defining the dose-response relationship between talc exposure and the risk of adverse health effects. The third step in a risk assessment is exposure assessment. In the current case, I was not attempting to define any specific exposure in quantitative terms but instead to use exposure assessment to define the type of information relevant to the product in question, a talc-based body powder. Therefore, exposure assessment involved defining the routes of human exposure that would be relevant for evaluating the risks posed by use of the powders. The last step in a risk assessment is risk characterization, a process where the scientist generates some statement about risk. This final step explains the outcome of the risk assessment in terms that explain the potential impact on health of the public, for example.

13. I was trained in the use of these methods as part of my undergraduate, graduate, and postdoctoral work in pharmacology and toxicology, as well as while working as a consultant

in human health risk assessment. Weight-of-the-evidence methodology, is used as part of regulatory decision making by regulatory and scientific bodies such as the FDA,[3] the U.S. Environmental Protection Agency (EPA),[4] and the U.S. Occupational Safety and Health Administration (OSHA),[5] and the World Health Organization (WHO) and the International Agency for Research on Cancer (IARC).[6] The *Reference Manual on Scientific Evidence* also describes the use of weight-of-the-evidence by experts in the process of evaluating a body of data or studies.[7]

14. At the end of this report is attached a list of the published scientific articles cited throughout this report. Attached to this report as Appendix C is a complete list of all materials that I have reviewed and/or relied upon in forming my opinions in this case. All the opinions expressed in this report are based on a reasonable degree of scientific certainty. I reserve the right to supplement and refine my opinions as additional relevant information becomes available.

III. Talcum Powder Products: The Regulatory Process in the United States

15. Johnson & Johnson talcum powder products entered the marketplace in 1894. At that time, the FDA did not exist and there was no law in place related to any type of product that is currently addressed by FDA regulations. Prompted by a series of food contamination issues, the Pure Food and Drugs Act was passed by Congress and signed into law in 1906 (Janssen 1981). This initial law was enforced by the Agriculture Department's Bureau of Chemistry and prohibited the introduction of "misbranded" and "adulterated" foods, drinks, and drugs into interstate commerce. In 1930, the Bureau of Chemistry became the Food and Drug Administration. In the decades that followed the passage of the 1906 law, scientists involved in administration of the law

[3] e.g., http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079257.pdf; http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm074916.pdf; http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079240.pdf

[4] e.g., https://www.epa.gov/sites/production/files/2015-06/documents/acephate-103301_2015-06-29_txr0057153.pdf; https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=23160&CFID=65932199&CFTOKEN=24176705; https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=71993&CFID=65932266&CFTOKEN=97071893

[5] https://www.osha.gov/weightofevidence/woe_guidance.pdf

[6] http://www.who.int/phe/news/events/international_conference/Session2_DrStraif.pdf

[7] The *Reference Manual on Scientific Evidence*, 3rd Edition. National Research Council. 2011. Washington, DC: The National Academies Press. https://doi.org/10.17226/13163.

were confronted with a series of public safety issues that included notably a drug-related tragedy (Sulfanilamide Elixir) and a cosmetic-related tragedy (Lash-Lure). In the case of the cosmetic product, a coal tar-based eyelash dye called Lash Lure caused serious eye injuries that included blindness and one death. Yet, it was the drug-related tragedy, where 107 people died, that purportedly led to passage of Food, Drug & Cosmetic Act (FDCA) in 1938 (Berger and Berger, 2017). Before the passage of the FDCA, there was no US law that addressed cosmetic safety specifically; the FDCA extended regulatory authority to cosmetics for the first time. The provisions of the 1938 Act that brought cosmetics under the purview of the FDA have changed little over the decades, in contrast to the multiple substantive changes in the law as it relates to other FDA-regulated products (*e.g.*, drugs, foods and medical devices).

16. As discussed in a review paper written in 1978 by the Commissioner of Food and Drugs (FDA), Dr. Kennedy, the author describes the process by which regulation of various product types evolved over the decades since 1938 (Kennedy, D. 1978). Dr. Kennedy describes how FDA moved forward over the years toward greater authority over drugs and medical devices, as well as foods, but not with respect to cosmetics. He describes the need for FDA to engage in something he termed "movement backward toward the source", where such actions are ones where FDA works to eliminate a public health threat using its existing statutory and research resources. As he stated in his paper:

> *"It is only in regard to cosmetics-regulated through the Bureau of Foods- that FDA has been frustrated in the necessary movement backward toward the source. While the Agency is charged with assuring that cosmetics are not harmful under conditions of use and are truthfully packaged and labeled, an anomaly in the Food, Drug, and Cosmetic Act places the burden on FDA to prove harm rather than on industry to prove safety, as is true with drugs and food additives…A study conducted by the General Accounting Office (GAO) pointed out that there is increasing evidence that some cosmetic products and ingredients carry a significant risk of injury to consumers and that, despite such evidence, efforts to regulate cosmetics have been hampered by the lack of adequate legislative authority…FDA's limited ability to reach back toward the source inhibits the Agency's ability to carry out risk assessment of cosmetic ingredients."* (see pages 611-612 of Kennedy, 1978).

The regulatory standards for cosmetics have remained essentially unchanged since the 1970's with some exceptions being: (1) in 1975 the FDA stipulated the need for warning statements on the label of cosmetics products and set forth the standards (March 3, 1975; 21 CFR 740); (2) in 1992 FDA initiated voluntary filing of cosmetic product composition statements for cosmetic products (57 FR 3129, Jan. 28, 1992; 21 CFR 720); (3) in 1974 FDA began voluntary registration of cosmetic manufacturing operations (39 FR 10059, Mar. 15, 1974; 21 CFR 710); and (4) in 1974 FDA required certain specifications for cosmetic labeling (39 FR 10056, Mar. 15, 1974; 21 CFR 701). As stated in 2012 testimony before Congress (CRS, 2012), *"FDA's authority over cosmetics is less comprehensive than its authority over other FDA-regulated products with regard to GMP; premarket notification, clearance, or approval; testing; and mandatory risk labeling."* The limitations on FDA authority over cosmetics is important in this case given that the Agency relies on cosmetic manufacturers and ingredient suppliers to ensure that the products marketed are safe for human use.

17. Over the years, the U.S. General Accounting Office (GAO) has been involved in evaluation of cosmetic regulations (GAO, 1978). The mission of the GAO is stated as follows: *"GAO exists to support the Congress in meeting its constitutional responsibilities and to help improve the performance and ensure the accountability of the federal government for the benefit of the American people."*[8] In its 1978 report, the GAO provided some important observations and suggestions on how to improve the process for protecting public health. The GAO reached the following conclusions in 1978 regarding cosmetic regulations:

> *"In spite of the significant risk of injury to consumers, the Food and Drug Administration (FDA) does not have an effective program for regulating cosmetics. The act does not authorize FDA to require manufacturers to register their plants or products, file data on ingredients, file reports of cosmetic-related injuries, or test their products for safety. Also, exemptions in the act do not permit effective regulation of coal tar hair dyes. FDA has not effectively used its existing authority. For example, it has not inspected most manufacturers' plants or sampled products for compliance with the act; it has established regulations governing the use of only 11 ingredients used in cosmetics; the safety of about*

[8] https://www.gao.gov/dsp/3mission.html

> *25 color additives has not been established; and it has had difficulty developing appropriate tests to be used by manufacturers in evaluating safety."*

The overall conclusion reached is reflected in the title of the report: "*Lack of Authority Hampers Attempts to Increase Cosmetic Safety*". The GAO also made recommendations that were stated as follows:

> *"The Congress should authorize the Food and Drug Administration to require cosmetic manufacturers to prove the safety of their products. Because the agency does not have enough authority to effectively regulate cosmetics, products are being marketed which may pose a hazard to consumers. About 125 ingredients available for use in cosmetics are suspected of causing cancer, and about 25 are suspected of causing birth defects. Although many of the reported adverse effects have not been verified, 30 of the ingredients are known to cause cancer in humans or animals or contain impurities known to cause cancer. The ability of these ingredients to cause toxic effects through cosmetic use has not been determined. Manufacturers do not have to determine the safety of their products before selling them or tell the Food and Drug Administration what products they are selling and what ingredients are used in them. Many manufacturers have not voluntarily given such Information to the agency. As a result, a hazardous cosmetic can be marketed until the Food and Drug Administration obtains information to prove that the product may be injurious to users."*

The discussion and findings by the GAO in 1978 are important context for understanding the responsibilities of cosmetic manufacturers and suppliers of cosmetic ingredients, such as Johnson & Johnson and Imerys, with respect to talcum powder products. The lack of FDA authority in key areas of cosmetic regulations that existed in the past, and exist even today, means that companies that market cosmetic products and ingredients must ensure that the products they sell are safe for use before they are marketed and continue to be safe for use as new scientific information becomes available.

18. With this historical context in mind, at issue in this litigation are cosmetic products known as talcum powder products. As mentioned above, current law does not require that

cosmetics or cosmetic ingredients have FDA approval before they enter the market.[9] Once cosmetic ingredients and products are marketed and placed into interstate commerce, the two important laws that pertain to the industry include the FDCA and the Fair Packaging and Labeling Act (FPLA). The FDCA defines cosmetics by their intended use, in the same way that other products (*i.e.*, drugs, device, foods, *etc.*) are regulated according to their intended use. A cosmetic is defined as follows: *"The term cosmetic means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."* (FDCA Section 201(i)). Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any ingredient intended for use as a component of a cosmetic product. The FPLA, enacted in 1967, directed the Federal Trade Commission (FTC) and the FDA to issue regulations requiring that *"consumer commodities"* be labeled to disclose net contents, identity of commodity, and name and place of business of the product's manufacturer, packer, or distributor.[10] In the case of cosmetics, the FDA was given responsibility for administering the law and for issuing regulations regarding labeling for foods, drugs, devices, and cosmetics.

19. Since the FDCA does not require that cosmetics undergo any type of approval by FDA before marketing, the focus of the regulations that have existed since passage of the law in 1938 has been to ensure that cosmetics are not *"adulterated"* and *"misbranded"*. The term *"adulterated"* with respect to cosmetics means that the product or an ingredient is known to pose a risk to human health, or the product is known to be unsanitary, or the product contains a prohibited ingredient, or the product is manufactured under unsanitary conditions (Jackson, E.M. 1995). The term *"misbranded"* means that the cosmetic product has false or misleading labeling, that the labeling fails to state information required by FDA (*i.e.*, name of product, net weight or amount of product, name of the company marketing the product, ingredients listed in descending

[9] https://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074162.htm
[10] https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/fair-packaging-labeling-act

order of amount, and any warnings about safety issues that the company is aware exist), or that the product packaging is misleading to the consumer in some way in terms of what it contains. FDA has published guidance on how to label cosmetic products.[11]

20. Unlike human drug products, both prescription and over-the-counter (OTC) products, there is no risk-benefit assessment performed as a part of a decision to allow a cosmetic product to be marketed. Cosmetics are not recognized to provide any health benefit, and, as a result, any significant health risks or concerns are unacceptable for such products. In the case of a drug, both FDA and the public understand that in some cases risks can be acceptable so long as there is some benefit assessment that outweighs that risk assessment. There are some products that are both cosmetics and drugs, and in those cases, the manufacturer must comply with both cosmetic and drug regulations.

21. It is the cosmetic manufacturer that is responsible for ensuring that its product and its ingredients are safe for use. The cosmetic ingredient supplier also has a duty to provide warnings related to the safety of the ingredients supplied to finished product manufacturers (*Federal Register* 40(42) March 3, 1975). The FDA does no testing itself. Instead, the FDA relies on companies to conduct all testing to ensure that the finished product, and its ingredients, are safe for human use. Therefore, as is stated by FDA:

> *"Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA."*[12]

As a result, manufacturers have a duty to conduct whatever testing is necessary to ensure the safety of their products and ingredients.

[11] http://www.fda.gov/downloads/Cosmetics/Labeling/UCM391202.pdf
[12] http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm

22. Another aspect of the FDA regulations pertaining to cosmetics that needs to be discussed is the standard for establishing a warning that would be placed on the labeling of a cosmetic product. It is important to realize that the standard for placing a warning on a cosmetic product is very different than the standard applied to products such as drugs. The standard applied to human prescription drug products in the US is as follows (21 CFR 201.57): *"The labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug;* ***a causal relationship need not have been definitely established****." [****emphasis*** *added]* In the case of cosmetic products and their ingredients, however, the warning standard is as follows: (21 CFR 740.1):

> *740.1 Establishment of warning statements*
>
> *(a) The label of* ***a cosmetic product shall bear a warning statement*** *whenever necessary or appropriate* to prevent a health hazard *that* ***may be associated*** *with the product.*
>
> *[****emphasis*** *added]*

This means that, unlike drugs, cosmetics are expected to carry warnings based on a standard of a possibility of health hazard, not on having evidence of a causal association between a health effect and the cosmetic product or ingredient. Not requiring proof of a cause and effect relationship is consistent with FDA's policy with drugs where causation does not need to have been proven before a warning may be placed on a drug product (see 21 CFR 201.57(c)). This issue is important in the current case involving talc cosmetic products and cancer risk because of the large body of evidence that developed over the decades providing evidence of increased risk of cancer with perineal use of talc body powder products---an important health hazard. Based upon the totality of the evidence reviewed there is **more than a possibility of a human health hazard**; these issues will be discussed in more detail below.

23. In the case of cosmetics, this reliance on industry for product safety assessments is especially important given that there is no Center for Cosmetics at FDA. Instead, the cosmetics regulations are enforced by the Office of Colors and Cosmetics that is within the Center for Food Safety and Applied Nutrition (CFSAN). As FDA has admitted, although the FDA has ways to monitor cosmetic products, available safety information is often limited (http://www.fda.gov/AboutFDA/Transparency/Basics/ucm262353.htm). The methods available

to FDA for monitoring cosmetic products include: (1) voluntary cosmetic registration program (VCRP); (2) inspections of facilities that voluntarily register with FDA; (3) surveys of product; (4) information conveyed in Cosmetic Ingredient Review (CIR) expert panel reviews;[13] and (5) spontaneous reports from consumers. In the case of the VCRP program, companies are not legally required to tell FDA anything about their products and the type of safety data that exists. Inspection of facilities is also not legally mandated, and, as acknowledged by FDA, due to limited resources "only a few establishments are inspected each year and just a fraction of imports are physically examined". Similarly, FDA has conducted surveys of marketed products by buying them and then examining them. This has mainly been done after some problem has been identified. The CIR panel process is an industry-funded process that typically is undertaken based on some impetus for review that is initiated within government, industry or the public. The spontaneous reporting by consumers to FDA is not required by law, and many consumers are unaware of the existence of the process for cosmetics.

24. There are some important constraints on FDA's authority as it relates to cosmetics. For example, any product recall of a cosmetic for a safety reason must be a voluntary action initiated by manufacturers or distributors to remove products from the market that may pose a hazard, that are marketed in a deceptive manner, or that are defective in some way (21 CFR 7.40(a)).[14] FDA can request such recalls but cannot require such recalls.

25. Unlike products such as drugs, devices and even foods, cosmetic manufacturers are not required to register the facilities where the cosmetics are manufactured.[15] This means that although FDA has the authority to inspect such facilities, unless the facility is registered, no inspections are made. In circumstances where an issue of product contamination or adulteration comes to light, FDA does have the authority to go and inspect facilities. This means that FDA is in the role of responding to problems, not preventing problems before they occur. Again, this is very different than the role FDA plays for other types of products.

[13] Although the FDA has access to, and can evaluate, the findings of a CIR review, such as the review for talc, the FDA does not adopt CIR findings. (See deposition testimony and exhibits of Dr. Linda Loretz dated October 2, 2018)

[14] https://www.fda.gov/cosmetics/complianceenforcement/recallsalerts/ucm173559.htm

[15] https://www.fda.gov/cosmetics/registrationprogram/default.htm

26. In 1997, FDA issued guidance to industry related to Good Manufacturing Practices (GMPs) for cosmetics.[16] The guidance has been updated as late as 2013. This guidance is non-binding but does lay out FDA's thinking in terms of how to properly manufacture, ensuring that cosmetics and their ingredients are safe for use in humans. This situation is unlike other FDA regulated products where there are mandatory GMP regulations that are actively enforced by FDA (*i.e.*, in the case of drugs, devices, and even foods).

27. Based on the general lack of regulatory oversight for cosmetics, it cannot be assumed that all marketed cosmetic ingredients and products are safe for human use. Additionally, it is likely that the public is unaware that FDA has strict limitations on its ability to ensure protection of public health when it comes to cosmetic products. With these regulatory limitations in mind, the chemical components of talc body powders and their hazards were considered and are discussed below with respect to the health hazards linked to the chemical components, the evidence linking cancer with exposure to chemical components of talcum powder products, and the need to provide warnings to consumers regarding health risks that may be linked to the chemical components of talcum powder products.

IV. Chemical Components of Talcum Powder Products and Their Hazards

28. The chemical nature of talc has been reviewed (*e.g.*, USEPA, 1992; IARC, 2010). Talc (CAS No. 14807-96-6), or magnesium silicate monohydrate, is a naturally occurring hydrous magnesium silicate compound with the chemical formula $3MgO•4SiO_2$. Like other minerals, talc can be classified by its structure, which consists of water molecules trapped between silicate sheets. This structure imparts the "feel" to talc, which is often referred to as slippery on the skin. Talc crystals are formed when these sheets stack upon each other. Talc can occur in non-plate forms as well. For example, asbestiform talc exists in nature, where asbestiform means the talc is in the shape of a fiber similar to the structure of asbestos. The structure of the talc particles, platy or fibrous, and the size of the talc particles, influence the toxicity potential of the talc powder.

[16] http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm353046.htm

29. As a mineral, talc is mined in countries around the world, including in the United States. Talc can be prepared to various specifications depending on the purity desired. Talcum powder products such as the ones manufactured and sold by Imerys and Johnson & Johnson were mainly platy talc but varied in their level of purity. In other words, talc powders were not 100% platy talc but contained levels of other co-occurring compounds such as talc containing asbestiform fibers (e.g., talc occurring in a fibrous habit), asbestos, nickel, chromium, and cobalt. These talc components are present in nature and are found in processed talcum powders. As a result, the purity of talcum powder products is an issue important to any safety assessment. It should be noted that talcum powder products manufactured decades ago were well known to contain asbestos as an impurity (EPA, 1992; IARC 2010). Contemporary cosmetic grade talcum powder products also have been shown to contain detectable levels of impurities that have included asbestos (Gordon *et al.* 2014). In 2009 and 2010, the FDA performed a survey where they examined 27 samples of cosmetic-grade raw talc and 34 talc-based products, including seven talc samples from Rio Tinto/Luzenac, one bottle of Shower to Shower, and one bottle of Johnson's Baby Powder, for the presence of asbestos.[17] FDA reported no detection of asbestos in the sample tested. However, as discussed by FDA: *"The results were limited, however, by the fact that only four talc suppliers submitted samples and by the number of products tested. For these reasons, while FDA finds these results informative, they do not prove that most or all talc or talc-containing cosmetic products currently marketed in the United States are likely to be free of asbestos contamination."* I considered these findings in light of the disclaimer, which acknowledge the limited sample size. As discussed in detail below, a review of internal company documents reveals that Imerys and Johnson & Johnson were aware that talcum powder products contained detectable levels of other toxic compounds that included but were not limited to fibrous talc, asbestos, chromium, nickel, and cobalt. There was one additional component of talcum powder products manufactured and sold by Johnson & Johnson, a fragrance component that contained many different chemicals (discussed below as well). Therefore, women using talcum powder products for genital dusting, or for application anywhere on the body, were exposed to a mixture of chemicals, not 100% pure platy talc. As a result, when performing a talcum powder product safety assessment, studies that describe talc products of varying purity levels were relevant to the assessment.

[17] http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm293184.htm

30. In the published medical literature, there is often discussion of talc using terms such as fibrous talc, asbestiform talc, non-asbestiform talc, or tremolite. Before discussing the literature on the toxicity of talcum powder products and its associated constituents it is useful to provide some background on the terminology of the mineral components of talcum powder products. As mentioned above, talc is one of a group of hydrous magnesium silicate minerals; its chemical formula is $Mg_3Si_4O_{10}(OH)_2$. Talc can occur as platy sheets of talc but also forms bundles of fibers (i.e., occur in an asbestiform habit), which consist of a group of individual elongate crystals. Asbestos is also a hydrous magnesium silicate mineral and has a chemical formula of $Mg_3Si_2O_5(OH)_4$. Like the term "talc", asbestos is the generic designation for a group of naturally occurring mineral silicate compounds that occur as fibers, either serpentine or amphibole fibers. The asbestos forms include the serpentine mineral chrysotile, and five amphibole minerals (actinolite, amosite, anthophyllite, crocidolite, and tremolite) (IARC, 2012). Chrysotile, lizardite, and antigorite are the three principal serpentine silicate minerals, but only chrysotile occurs in the asbestiform habit (USGS, 2001). In the amphibole series, amosite and crocidolite occur only in the asbestiform habit, while tremolite, actinolite and anthophyllite occur in both asbestiform and non-asbestiform habits. As discussed in older published literature, fibrous talc was often a term used to refer to any form of fiber in talc, including asbestos (Rohl *et al.* 1974). As a result, in this report, care was taken to use these terms when referring to the detection of fibers: asbestos, non-asbestiform talc (platy talc), and talc containing asbestiform fibers (fibrous talc).

31. Since talc occurs as a particle in nature, the biological effects of talc, including its adverse effects or toxic effects, are related to both its chemical composition and its physical structure. This is a general principle of toxicology that relates to tissue contact with chemical particles.[18] The biological effects and toxicology of talc have been reviewed (IARC, 1987; USEPA, 1992; IARC, 2010). The types of effects observed depend, in part, on the route of exposure. As a mineral, talc has the propensity to produce an irritant and inflammatory response at sites of exposure (reviewed in EPA, 1992; discussed in more detail below). It is the irritant and inflammatory properties of the mineral that the scientific literature indicates underlie many of the human health risks associated with talc exposure (as reviewed in IARC, 1987; EPA, 1992; IARC,

[18] http://ehs.unl.edu/documents/tox_exposure_guidelines.pdf

2010; discussed in more detail below). The presence of fibers in talc is important because exposure to fibers is known to cause adverse biological effects in cells and tissue. This is driven in part by the fact that the tissue response to a fiber as compared to a particle is affected by the ability of immune cells to engulf the fiber (Fubini and Fenoglio, 2007). If the fiber is long, immune cells cannot totally engulf the compound and remove the foreign material from the tissue. As a result, there are similarities in the potential adverse effects that are associated with any fibrous mineral, both talc and asbestos.

32. Given that talc used to manufacture body powders has the potential to be a mixture of toxic compounds, it is important to understand the constituents of commercially available talcum powder products manufactured and sold by Imerys and Johnson & Johnson. Johnson & Johnson was aware that asbestos or asbestiform fibers were present in talc that was mined for talcum powder products (*e.g.*, JNJ000251888). When commercially available talcum powder products have been analyzed, including powders sold by Johnson & Johnson, the data has shown that the powders contain variable levels of fibers, including fibers that were stated to be asbestos (*e.g.*, Paoletti *et al.* 1984; Blount, 1991; Mattenklott *et al.* 2007; Moon *et al.* 2011; Gordon *et al.* 2014; Anderson *et al.* 2017; Rohl *et al.* 1976; Pooley and Rowlands, 1975; Blejer and Arlon, 1973; Cralley, *et al.* 1968; Millman, N. 1947; JNJ000025132; IMERYS205540-554; IMERYS136824; IMERYS265938-993; IMERYS245144; JNJ000375389-390; IMERYS240376-378; IMERYS240406; IMERYS213431-433; JNJNL61_000052427; JNJNL61_000042576; IMERYS138505-511; IMERYS100130-150; JNJMX68_000004996-5031; JNJTALC000301172-1179; JNJ000264653-4655; JNJNL61_000033289-3292; JNJTALC000293589-591; JNJTALC000292656-657; IMERYS051370-374; IMERYS219720-722; JNJ000062359-363; JNJ000062436; JNJ000063951; JNJ000064544; JNJ000065264-266; JNJ000277941-943; JNJ000314315-316; JNJ000314406-414; JNJAZ55_000000905-948; JNJAZ55_000004563; JNJMX68_000003728; JNJMX68_000013019-020; JNJNL61_000079334; JNJMX68_000020276-282; JNJ000231304-318; IMERYS-MDL-AB_0006980; IMERYS 210136). In more recent work related to this litigation, scientists have found that samples of Johnson & Johnson body powder products that were examined contained

fibrous talc (see April 28, 2017 report by Longo and Rigler[19] where 8 of 11 samples contained fibers; August 2017 report by Longo and Rigler[20] where 14 of 30 samples contained fibers). Dr. Longo's testing of talcum powder samples produced in the MDL revealed that 37 of 56 samples contained asbestos and 41 of 42 observed to contain asbestiform talc. Although companies have claimed that talcum powder products manufactured after the mid-1970's were free of asbestos, asbestos fibers have been found in products in the marketplace after that time (*e.g.*, Paoletti *et al.* 1984; Blount, A.M. 1991; Mattenklott *et al.* 2007; Moon *et al.* 2011; Anderson *et al.* 2017; Egilman and Steffen, 2018; February 16, 2018 report of Longo and Rigler;[21] IMERYS095086-087; IMERYS136824; IMERYS245144; JNJ000375389-390; IMERYS213431-433; JNJNL61_000014431-14437; IMERYS219720-722). These published scientific studies, internal testing documents, and testing results by Longo and Rigler show that asbestos has been consistently present in Johnson & Johnson's talcum powder products since the mid-1950's and certainly after the 1970's when the defendants represented that asbestos had been eliminated from talcum powder products (additional support found within the exhibits and deposition testimony of Ms. Julie Pier, dated September 12, 2018; and Dr. John Hopkins, dated August 16 & 17, 2018; October 17, 2018, and November 5, 2018). The presence of asbestos was evident before the 1970's and after that time as well. It is important to note that talc containing asbestiform fibers was classified in 1986 as a known human carcinogen (IARC, 1987, 2010, 2012). Talc containing asbestiform fibers was listed by the State of California (PROP 65) in April 1990 as a chemical *"known to the State to cause cancer"*.[22] The National Institute for Occupational Safety and Health (NIOSH) has stated that there is no safe level of asbestos exposure (NIOSH, 1980). This means that human exposure to even very low levels of asbestos increase the risk of toxic effects including cancer.

33. With respect to asbestos as a constituent of talcum powder products, it had been known at least by the 1930's that asbestos exposure caused lung disease (*e.g.*, Cooke, W.E. 1927; Oliver, T. 1927; Seiler, H.E. 1928; Wood, W.B. 1929; Merewether and Price, 1930; Merewether,

[19] The report is entitled "Analysis Report: MAS Project # 14-1683 Johnson's Baby Powder Sample Set.
[20] The report is entitled "Analysis of Johnson & Johnson Baby Powder and Valiant Shower to Shower Products for Amphibole (Tremolite) Asbestos".
[21] The report is entitled "TEM Analysis of Historical 1978 Johnson's Baby Powder Sample for Amphibole Asbestos".
[22] https://oehha.ca.gov/media/downloads/crnr/p65list052518.pdf

E.R.A. 1930; Gloyne, S.R. 1935). As one author described the issue of asbestos exposure and lung disease, *"**widespread recognition of asbestosis** dates from the work of Merewether and Price in 1930 [**emphasis** added]"* (Hourihane and McCaughey, 1966). Additionally, it was known at least by the 1950's that asbestos exposure could cause lung cancer (*e.g.*, Gloyne, S.R. 1935; Doll, R. 1955; Selikoff *et al.* 1964). Additionally, ,some studies have reported an increased risk of ovarian cancer in women exposed to asbestos (*e.g.*, Keal *et al.* 1960; Graham and Graham, 1967; Newhouse *et al.* 1972; Acheson *et al.* 1982; Wignall and Fox, 1982; Newhouse *et al.* 1985; Tarchi *et al.* 1994; Bulbulyan *et al.* 1999; Germani *et al.* 1999; Magnani *et al.* 2008; Bunderson-Schelvan *et al.* 2011; Camargo *et al.* 2011; Wang *et al.* 2013; Ferrante *et al.* 2017). Regulatory authorities world-wide have identified asbestos as a known human carcinogen (*i.e.*, IARC, 1987; IARC, 2012; ATSDR, 2001; EPA, 1984; NTP, 2016; Canada[23]; European Union[24]; Australia[25]). Given the well-known toxic effects and human health risks associated with asbestos, the presence of asbestos fibers in talcum powder products is a significant risk to human health.

34. There is a fragrance component added to all Johnson & Johnson talcum powder products. In the document entitled *"Defendant Johnson & Johnson Consumer Inc.'s Supplemental Answer to Plaintiffs' Second Set of Interrogatories No. 19"* dated December 21, 2017, Johnson & Johnson provided a list of fragrance chemicals that are added to Johnson's Baby Powder® products and a list of chemicals that had been added to Johnson & Johnson's Shower-To-Shower® products. Over 50 fragrance chemicals were listed as having been added to the Shower-To-Shower products while more than 130 fragrance chemicals were listed as being currently used in Johnson's Baby Powder. This means that any bottle of talcum powder sold to consumers contained many different chemicals, not simply platy talc. It should be noted that recent changes to the Johnson & Johnson website provide disclosure to consumers of what is claimed to be "100%" of their fragrance ingredients.[26] The list on the website, however, is not the same as the list provided in the 2017 documents discussed above, and the website also fails to provide information on the fragrance chemicals used in the past. Both sources of information, the 2017 document produced by Johnson & Johnson and their updated website, fail to provide specific information on the amount of each

[23] https://www.canada.ca/en/health-canada/services/air-quality/indoor-air-contaminants/health-risks-asbestos.html
[24] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Aem0032
[25] https://www.safeworkaustralia.gov.au/asbestos
[26] https://www.johnsonsbaby.com/our-mission/scents-fragrance

chemical component in the fragrance component of either Johnson's Baby Powder or Shower-To-Shower.

35. A review of the chemicals listed in the 2017 document reveals that, in many cases, the compounds listed are known to have toxic properties. In fact, of the fragrance chemicals listed, several have been associated with potential carcinogenic activity. These include ethenyl benzene, also known as styrene, and *p*-cresol (4-methylphenol). Styrene is a compound that has been classified by the National Toxicology Program (NTP) as "reasonably anticipated to be a human carcinogen"[27], and classified by IARC as a 2A carcinogen (probable human carcinogen)[28]. In the case of *p*-cresol, EPA has determined that it is "possibly carcinogenic to humans".[29] Other chemicals listed as being a part of the fragrance component of Johnson & Johnson talc body powders have been reviewed by IARC for cancer potential (coumarin, eugenol, d-limonene; all given a Category 3 classification of "not classifiable")[30]. A cancer risk, however, is not the only human health risk linked to the numerous fragrance chemicals present in Johnson & Johnson talc body powder products. Even a cursory search of the scientific information available on either non-governmental sites or regulatory authority sites[31] shows that most of the chemicals are known individually to have irritant properties and/or inflammatory properties when in contact with cells and tissues. Of the more than 100 chemicals included in the 2017 list of fragrance ingredients, over 70% are compounds that have been linked with some level of irritant hazard to tissues (skin, eye, mucous membranes; see Appendix D to this report; Report of Dr. Michael Crowley). The issue of irritant properties will be discussed below as it relates to carcinogenesis and mechanisms for cancer linked to talc and the chemical components of talc. Yet, consumers have never been provided with information that any of the ingredients in the Johnson & Johnson fragrance posed a potential human health risk.

[27] https://ntp.niehs.nih.gov/ntp/roc/content/profiles/styrene.pdf; https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=74
[28] https://monographs.iarc.fr/list-of-classifications-volumes/
[29] https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=196
[30] https://monographs.iarc.fr/wp-content/uploads/2018/06/ClassificationsAlphaOrder.pdf
[31] Searches of publicly available databases were performed including TOXNET, PUBCHEM, HSDB, The Good Scents Company (www.thegoodscentscompany.com), the Environmental Working Group (https://www.ewg.org/), cosmeticsinfo.org (PCPC sponsored site), and the Cosmetic Ingredient Review (https://www.cir-safety.org).

36. In addition to the presence of asbestos in talcum powder products and the presence of dozens of fragrance chemicals, evidence shows that the products manufactured by Imerys and sold by Johnson & Johnson contained detectable levels of heavy metals (*e.g.*, JNJ000245268-274; JNJMX68_000004996-5031; IMERYS223869-883; IMERYS265938-993; IMERYS194090-095; IMERYS032928; IMERYS094601; IMERYS053387-88; IMERYS098115-116; IMERYS219720-722; IMERYS304036; IMERYS-A_0015663; JNJ000265171; JNJTALC000869376; JNJ000025132; JNJ000347962-963; P-68; exhibits and deposition testimony of Ms. Julie Pier dated 9/12/2018; Cralley *et al.* 1968a; Pooley and Rowlands, 1975; Rohl *et al.* 1976; Gondal *et al.* 2012; Rehman *et al.* 2013). The levels of heavy metals have varied across different processed lots of talcum powders, but internal company documents show that certain heavy metals have been repeatedly detected, such as chromium (Cr), cobalt (Co), and nickel (Ni). These heavy metals are known to be toxic to human cells and tissues. Some of these heavy metals are known to be carcinogenic in animals and/or humans. Chromium (Cr) and nickel (Ni) have been classified as *"known human carcinogens"* by IARC[32]. Cobalt (Co) has been classified by IARC as Group 2B, or *"possibly carcinogenic to humans"*.[33] The NTP has listed chromium (Cr) and nickel (Ni) as *"known to be human carcinogens"*, while cobalt is listed as *"reasonably anticipated to be human carcinogens"*. [34]

37. Focusing now on talc itself as a toxic compound, a review of the scientific literature reveals that in many cases, the compound being tested or discussed is usually described simply as talc, with no description of the purity or physical state of the compound (fibrous or platy). In the following discussion of the literature that relates to the toxicity of talc, I will mention the specific type of talc (*i.e.*, mined talc, milled talc, fibrous talc, talc of certain purity levels, cosmetic grade talc, *etc.*), if reported.

38. A review of the published scientific literature shows that the human health hazards associated with exposure to talc dust has been known for decades, well before the 1970's. In fact, as far back as the first half of the 20th century (before 1950), scientists had discovered that:

[32] https://monographs.iarc.fr/wp-content/uploads/2018/06/ClassificationsAlphaOrder.pdf
[33] https://monographs.iarc.fr/wp-content/uploads/2018/06/ClassificationsAlphaOrder.pdf
[34] https://ntp.niehs.nih.gov/ntp/roc/content/listed_substances_508.pdf

- talc particles produced adverse tissue reactions in cells or tissues, and in humans and animals (*e.g.*, tremolite talc: Dreessen, W.C. 1933; Miller and Sayers, 1936; Greenburg, L. 1947; mining talc: Porro *et al.* 1942; Porro and Levine, 1946; Schepers and Durkan, 1955; industrial grade talc: Schulz and Williams, 1942; McLaughlin *et al.* 1949; Jaques and Benirschke, 1952; Sax, I. 1957; cosmetic grade talc: Roberts, 1947; Saxen and Tuovinen, 1947; Eiseman *et al.* 1947; U.S. Patent No. 2,621,333 filed June 27, 1947; Eberl *et al.* 1948; Graham and Jenkins, 1952; U.S. Patent No. 2,626,257 filed May 21, 1952 by Johnson & Johnson; Cless and Anger, 1954; Creery *et al.* 1957; Sax, I. 1957);
- exposure to talc dusts in an occupational setting was linked to an increased risk of lung disease, including cancer (*e.g.*, tremolite talc: Dreessen, W.C. 1933; Greenburg, L. 1947; mining talc: Dreessen and Dalla Valle, 1935; Porro *et al.* 1942; Porro and Levine, 1946; Kleinfeld *et al.* 1955; Schepers and Durkan, 1955; industrial grade talc: McLaughlin *et al.* 1949; Hogue and Mallette, 1949; Jaques and Benirschke, 1952; Mann and Deasy, 1954; Seeler *et al.* 1959; cosmetic grade talc: Millman, N. 1947);
- the risks associated with occupational exposures to talc were higher when fibrous forms of magnesium silicate minerals (talc as well as asbestos) were present (*e.g.*, Dreessen and Dalla Valle, 1935; Schulz and Williams, 1942; Saxen and Tuovinen, 1947; Millman, N. 1947; Greenburg, L. 1947; Hogue and Mallette, 1949; Schepers and Durkan, 1955); and
- exposure to cosmetic grade talcum powders themselves were associated with adverse tissue responses and adverse human health effects, including cancer in some cases (*e.g.*, Roberts, G.B. 1947; Greenburg, L. 1947; Eiseman *et al.* 1947; U.S. Patent 2,621,333; Eberl, 1948; Graham and Jenkins, 1952; U.S. Patent No. 2,626,257; Cless and Anger, 1954; Creery *et al.* 1957).

39. Then, when reviewing the scientific literature available since 1960, the evidence has continued to accumulate showing that:

- talc has adverse effects in cells, tissues, animals and humans (*e.g.*, cosmetic grade talc: Molnar *et al.* 1962; Blumel *et al.* 1962; Jenkins, M.Q. 1963; Tye *et al.* 1966; Trautwein and Helmboldt, 1967; Migaki and Garner, 1969; Merliss, R.R. 1971; Pott and Friedrichs, 1972; Wagner *et al.* 1975; Stenback and Rowland, 1978; Kaiser *et al.* 1982;

Davies *et al.* 1983; Hamilton *et al.* 1984; Stenback *et al.* 1986; Pelling and Evans, 1986; NTP, 1993; Hamilton *et al.* 2001; Buz'Zard and Lau, 2007; Shukla *et al*. 2009; Shim *et al.* 2015; Fletcher *et al.* 2018; Fletcher and Saed, 2018; mining or milling talc: Kleinfeld *et al.* 1963; Beck *et al.* 1987; unspecified: Henderson *et al.* 1971; Blejer and Arlon, 1973; Pott *et al.* 1974; Henderson *et al.* 1979; Abraham and McEuen, 1986);

- exposure to talc dusts in an occupational setting was linked to an increased risk of lung disease, including cancer (*e.g.*, mining or milling talc: Kleinfeld *et al.* 1963; Kleinfeld *et al.* 1964; Kleinfeld *et al.* 1967; Kleinfeld *et al.* 1973; Rubino *et al.* 1976: cosmetic grade talc: Miller *et al.* 1971; Nam and Gracey, 1972);
- the risks associated with occupational exposures were higher when fibrous forms of magnesium silicate minerals (talc as well as asbestos) were present (*e.g.*, Kleinfeld *et al.* 1963; Kleinfeld *et al.* 1964; Pott and Friedrichs, 1972; Blejer and Arlon, 1973; Pott *et al.* 1974; Wagner *et al.* 1975; Stanton *et al.* 1981), being linked to fibrotic diseases of the lungs, such as talcosis and pneumoconiosis (*e.g.*, Dreesen and Dalla Valle, 1935; Porro and Levine 1946; Greenburg, 1947; Kleinfeld et al. 1973); and
- exposure to cosmetic grade talcum powders themselves were associated with adverse tissue responses and adverse human health effects, including deaths in some cases (*e.g.*, Molnar *et al.* 1962; Blumel *et al.* 1962; Jenkins, M.Q. 1963; Hughes and Kalmer, 1966; Migaki and Garner, 1969; Moss, 1969; Miller *et al.* 1971; Nam and Gracey, 1972; Wagner *et al.* 1975; Brouillette and Weber, 1978; Mofenson *et al.* 1981; Cramer *et al.* 1982; Kaiser *et al.* 1982; Pelling and Evans, 1986; Kupryjanczyk, 1989; Buz'Zard and Lau, 2007; Shukla *et al.* 2009; Shim *et al.* 2015).

Also relevant to this discussion of what was known based on review of studies published in the scientific literature is the fact that Johnson & Johnson itself published a review article in 1976 (Hildick-Smith, 1976). In that paper, Dr. Hildick-Smith provided a summary of the scientific literature from the 1940's to the 1970's, listing many studies that provide proof that talc has toxic properties at certain doses and by different routes of exposure, *i.e.*, talc itself is a toxic compound.

40. Considered together, there is a large body of reliable scientific information, of all types (studies in cells, tissues, animals and humans), that identifies talcum powder products as

posing a hazard to human health. The types of toxicity produced are dependent on the route of exposure and the purity of the talc product. Yet, there is no controversy concerning the existence of a hazard and a need to control exposures to talc dusts and powders. Exposure to talc body powders internally (direct tissue contact) can cause a variety of adverse effects that are related to the known irritant and inflammatory properties of talc itself as well as the presence of other chemical components that exist in cosmetic grade talcum powder products.

V. Talcum Powder Products: Perineal Application and Internal Exposure

41. The human health concern with talcum powder products in the current case is ovarian cancer in women who applied the products repeatedly to the perineal area. The first step to consider in the process of producing ovarian cancer with perineal talc dusting is exposure. Although dermal exposure is also a potential route of concern, the absorption of talc particles across skin has been assumed to not be of consequence when assessing toxicity of talcum powder products unless the skin has been damaged in some way. Instead, exposure assessments of talc applied dermally have focused on entry into the body through portals such as the lungs, the vagina or the mouth (IARC, 1987; EPA, 1992; IARC, 2010). The toxicity potential of talc has been shown to be affected by the route of exposure, with more significant toxicity linked to penetration of small talc particles into tissues and triggering of cytotoxic responses at the local site of tissue interactions (EPA, 1992). Therefore, consistent with existing data, talc would be less toxic following oral exposure where the interaction with stomach acids, and presence of the gastrointestinal barrier, would affect the expected toxicity potential.

42. When assessing the potential for human exposure to talc applied to the perineal area, the focus has been on entry into the body through the vagina. There also is evidence that application of talcum powder products results in inhalation exposure of talc dusts (*e.g.*, the September 2017 study by Longo and colleagues entitled "*Below the Waist Application of Johnson & Johnson Baby Powder*"; Jasuja *et al.* 2017; Frank and Jorge, 2011; van Huisstede *et al.* 2010; Wells *et al.* 1979). An early study by the National Institute of Occupational Safety and Health (NIOSH) in 1972 showed that talcum powder products samples available commercially contained fibers and that exposure to fibers would occur during diapering (JNJ000231304-318); this study was received by Johnson and Johnson at least by March of 1974. Based on its chemical nature,

talc delivered as a powder in consumer products can be inhaled while being applied (EPA, 1992; IARC, 2010). Regardless of the portal of entry, lungs versus the vagina, talc-induced local tissue toxicity would be expected to be produced in tissues that are accessed following perineal dusting with talc. With respect to inhalation exposure of talcum powder products and the potential for inhaled particles to migrate to the ovaries, studies have shown that asbestos fibers can move from the lung to other body organs via the lymphatic system (Suzuki and Kohyama, 1991; Bunderson-Schelvan et al. 2011). The lymphatic system is known to be involved in the transport of inhaled particles from the lung to distant sites (Leak, L.V. 1980; Stuart, B.O. 1984; Adamson and Prieditis, 1998; JNJ000046293). Thus, it is biologically plausible that talc particles that embed or deposit within lung tissue could be transported away from the lungs through the lymphatic system in the same way that other particles, and even asbestos, have been shown to travel to sites distant from their portal of entry, the lungs. With respect to genital dusting of talcum powder products, I considered the available evidence related to the ability of talc to migrate from the site of application, *i.e.*, perineal or vaginal application, to the ovaries.

43. The migration of talc internally after perineal application was discussed by scientific and regulatory bodies that reviewed the toxicokinetics of talc (EPA, 1992; IARC, 2010) as well as by FDA in a recent letter (FDA, 2014). As FDA concluded in 2014, *"…**the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable**. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers." [**emphasis** added]*. A review of the scientific literature revealed that FDA's conclusion is supported by a variety of studies that include, but are not limited to, studies examining or reviewing the migration of particles in humans (*i.e.*, Egli and Newton, 1961; de Boer, 1972; Parmley and Woodruff, 1974; Venter and Iturrulde, 1979; Blumenkrantz *et al.* 1980; Gardner *et al.* 1981; Iturralde and Venter, 1981; Holme *et al.* 1984; McCalley *et al.* 1985; Wright *et al.* 1996; Kunz *et al.* 1996; Heller *et al.* 1996; Kunz *et al.* 1997; Kadanali *et al.* 2001; Kunz and Leydendecker, 2001; Kissler *et al.* 2004; Sjosten *et al.* 2004; Kunz *et al.* 2007; Zervomanolakis *et al.* 2007). Additionally, authors have described the potential for abdominal exposure to talc particles following perineal application of talcum powder products in women (Longo and Young, 1979);

the abdominal cavity in humans is reached directly through migration of particles from the vagina, through the reproductive tract and up towards the ovaries, which are suspended within the peritoneal space. These studies are important because they demonstrate that inert particles routinely move from the lower female reproductive tract (vagina) up into fallopian tubes and towards the ovaries. There also are data demonstrating the presence of talc particles in the ovaries of women who had reported use of talcum powder products on the genital area (*e.g.*, Heller *et al.* 1996; Cramer *et al.* 2007), as well as animal studies showing that in some species talc can migrate from the lower to the upper genital tract (*e.g.*, Phillips *et al.* 1978; Gardner *et al.* 1981; Henderson *et al.* 1986; Edelstam *et al.* 1997). Given the differences between animals and humans in terms of anatomy of the genital tract, the studies in humans are the most reliable in terms of human health risk assessment and the toxicokinetics of talc applied externally to the perineal area. The weight-of-the-evidence shows that inert particles routinely move from the lower female reproductive tract (vagina) up into the uterus, the fallopian tubes and towards the ovaries. Therefore, in terms of the potential for exposure following perineal application of talc body powders, the available data support statements by the FDA that particulates can move from the vagina up the reproductive tract in women to provide for exposure to internal organs, including the ovaries.

44. An early study examining the issue of migration of substances through the female reproductive tract was undertaken to better understand the time relationships and precise mechanisms of transport of inert particles or spermatozoa in humans (Egli and Newton, 1961). The study was designed to determine whether, under reasonably controlled conditions, carbon particles could be transported quickly from the vagina to the fallopian tubes. Three women who were scheduled for hysterectomy voluntarily participated and were administered carbon particles under anesthesia after being positioned on their backs. Three to four milliliters of sterile carbon particles in a Dextran suspension were deposited in the upper portion of the vagina. Oxytocin was administered intra-muscularly at that time as well. Immediately after injection, the fallopian tubes were removed and examined for the presence of carbon particles; a very short time was allowed for potential transport. In two of the three women, carbon particles were recovered from the fallopian tubes 28 and 34 minutes after injection into the vagina. The authors concluded: "*These data, together with other work in animals and humans, support the belief that the motility of spermatozoa is not the chief factor in sperm transport.* ***Contractions of the muscle of the uterus***

or other reproductive organs may be very important*, and it is possible that oxytocin may play a part in this process."[**emphasis** added]* A similar study was performed a decade later (DeBoer, 1972) where the author reported on the movement of carbon material up the genital tract in a series of patients undergoing abdominal surgical procedures. The women were injected (some cervical instillations and some uterine instillations) with a colloidal carbon suspension (India ink), and in some cases women also were given an injection of oxytocin. Surgeries were performed at various times after injection, from 15 minutes l to 24 hours after injection. The authors stated *"…**there was no doubt that the inert carbon material was frequently and rapidly transported from the uterus to the tubes** in both phases of the menstrual cycle." [**emphasis** added]* Passage of particles from the vagina to the uterus was observed in two of 37 patients examined, while particles were detected in the fallopian tubes in 30% of patients with cervical instillation and in 50% of patients with uterine instillation. Two years later, the migration of environmental substances externally in women was discussed in connection with the origins of ovarian mesotheliomas (Parmley and Woodruff, 1974). In the discussion section the authors stated: *"The uniqueness of the female peritoneal cavity is that **environmental substances may more easily reach it by passage through the vagina and Fallopian tubes** (Fig. 13). Conversely, no such entry is available in the male…" [**emphasis** added]* All three of these studies provided early notice of the ability of particles to move up the female reproductive tract.

45. In addition to studies in humans, experiments were conducted in different animal species to examine the ability of talc to be distributed beyond the site of exposure, oral or intra-vaginal application (Phillips *et al.* 1978). As discussed by the authors, their studies were prompted by the safety concerns raised in the scientific literature with respect to talc, specifically they indicate that *"the possibility of a causal relationship between particular types of tumours and the presence of talc has caused disquiet about its safety-in-use"*. With respect to the issue of movement of talc within the reproductive tract, rabbits were administered either a single intra-vaginal dose (50 mg total talc in 0.5 ml volume; three rabbits tested) or six daily doses of the same amount of talc (also 3 rabbits). In all cases, the animals were sacrificed 72 hours after the dosing ceased. The urogenital tracts were dissected to determine if radioactivity could be detected. After one dose of radiolabeled talc, radioactivity was detected only in the vagina. In the rabbits administered multiple doses of radiolabeled talc, radioactivity was detected at the site of application but also in the cervix,

the uterus and the fallopian tubes, but not the ovaries. Thus, migration or translocation occurred in the rabbit reproductive tract to a limited extent, although not all the way to the ovaries. Even though studies in animals are not ideal in terms of modeling the female reproductive tract, this study again provided notice of the ability of particles to move within the reproductive tract.

46. In another human study in 1979, scientists reported use of a radionuclide procedure designed to evaluate the migration of a particulate radioactive tracer from the vagina to the peritoneal cavity and ovaries, as well as the determination of the patency of the pathways between these two extremes of the female reproductive system (Venter and Iturralde, 1979). The procedure employed radiolabeled human albumin microspheres that were deposited into the vaginas of 24 patients one day before they were to undergo a gynecological surgery. Sequential images were obtained during the 24-hour period, and after the surgeries were completed radioactivity levels in the removed organs and tissues were counted with a scintillation detector. The authors reported that in 14 out of 21 cases it was possible to measure radioactivity levels in the adnexa (*i.e.*, fallopian tubes, ovaries) separately from the uterus. Nine patients showed marked radioactivity in the tubes and ovaries, while in five patients the radioactivity levels were not much higher than the background. In all five of these patients with background levels of radioactivity detected, the authors reported that severe tubal occlusion was confirmed. As the authors discussed: *"**Evidence is available for migration of different substances in either direction within the female reproductive system** between the peritoneal cavity and ovaries via the tubes, uterus and vagina, and the outside. Various living organisms actively follow this pathway in both directions. Gases, fluids, dyes and contrast media can easily be introduced from the vagina into the peritoneal cavity. **If transit can take place so easily, it is probably the same for many chemical substances used for hygienic, cosmetic or medicinal purposes, many of which may have potential carcinogenic or irritating properties**." [**emphasis** added]* This paper provided evidence that migration of talc upwards into the female reproductive tract was considered more than a possibility at this point in time.

47. In a similar study reported in 1985 (McCalley *et al.* 1985), scientists performed a prospective study to evaluate the efficacy of radionuclide hysterosalpingography (RNHSG) using a technique with some modification that had been described by Venter and Iturralde (1979). The

authors state: *"As these investigators demonstrated, technetium labeled human albumin microspheres will* ***normally migrate spontaneously from the vagina to the ovaries****." [****emphasis*** *added]* This new study confirmed the findings of the 1979 study and showed that if the fallopian tubes are not patent, migration cannot continue. Most importantly, the authors provided the following conclusions: *"Our work confirms the observation of Iturralde and Venter that inert particles are easily and spontaneously transported from the vagina through the genital tract to the ovaries. This implies that sperm motility, although possibly essential, e.g., for penetration of the ovum, may not be the basic factor in sperm transport.* ***It also confirms that pathogenic materials deposited in the vagina can be transported onto the ovary and may play a role in the etiology of some ovarian carcinomas.*** *[emphasis added]* The scientific studies providing notice on the ability of particles to migrate continued to build.

48. Another source of human data related to migration of substances upwards in the female reproductive tract is found in a book chapter that was prepared from a presentation made at the 7th International Symposium on Controlled release of Bioactive Materials (July 27-30, 1980) (Gardner *et al.* 1981). The chapter provides an overview of what was known at the time regarding movement of particles and other materials up the female reproductive tract from the vagina. The chapter was focused on using that route of exposure as a method for delivery of drugs in women. The author stated: *"The concept of a particulate drug-delivery system is further supported by studies in humans, which* ***demonstrate the movement of inert particles through the reproductive tract****. Following placement in either the vagina, cervix, or uterus, particles such as carmine or carbon black have been observed to* ***migrate into the fallopian tubes or peritoneal cavity****." [****emphasis*** *added]* Additionally, the authors described new studies in Stumptail monkeys. They reported that vaginally delivered drug particles were able to migrate through the cervix into the uterus. They stated: *"Transcervical migration from the vagina to the uterus (24 hours post-insertion) was observed to some degree in six out of eleven animals. In these studies, it appeared that capsule diameters less than 300 microns in diameter showed preferential migration. However, one animal out of three at the largest capsule diameter did show migration of greater than three percent of the inserted microcapsules."* In a study in one baboon, the authors reported that six hours after insertion of two different sizes of tracer microcapsules there was essentially no difference in transcervical migration between the two sizes, and that migration was rapid (within

six hours) into the cervix, uterus, and fallopian tubes. These studies provided additional evidence for migration of substances from the vagina upwards into the reproductive tract, including a study in primates.

49. Three additional animal studies appeared in the scientific literature in 1985 and 1986 that are relevant to the issue of talc migration in the female reproductive tract (Wehner *et al.* 1985; Henderson *et al.* 1986; Wehner *et al.* 1986). Henderson and colleagues from the Tenovus Institute reported on the ability of talc to migrate from the vagina to the ovary in rats (Henderson *et al.* 1986); this same research group had published data on the finding of talc in the human ovary (Henderson *et al.* 1971; Henderson *et al.* 1979). The authors stated: "***Direct communication between the external environment and the peritoneal cavity*** *exists in the female via her genital tract." [**emphasis** added]* The study was undertaken after Henderson and colleagues (1984) showed that injection of talc beneath the bursal sac around the ovary in rats was accompanied by *"associated epithelial changes not inconsistent with the histological picture of premalignancy."* In the first of this new set of experiments by Henderson and colleagues in 1986, eight rats received intra-uterine talc (100 mg/ml suspension; 250 µl volume) injections. Rats in Group I (four rats) were sacrificed five days after talc exposure, and their ovaries were removed. Rats in Group II (four rats) received further talc uterine injections six days or 15 days after initial treatment. On day 20, two rats were sacrificed, and the remaining two rats were sacrificed 22 or 30 days after initial treatment. In all cases, ovaries were removed and analyzed for the presence of talc particles. In a second experiment employing vaginal delivery of talc, twelve rats were divided into two groups of six. Rats in Group I had a 250 µl suspension of talc (100 mg/ml) deposited into their vagina, while rats in Group II received vehicle treatment. Two animals in each group were sacrificed 24 hours, 48 hours and four days after treatment. Their ovaries were removed and processed for detection of talc particles. Particles of talc were identified in the ovaries of all rats at all time points where talc had been instilled into the uterus. With vaginal instillation, talc particles were detected in two of the animals when sacrificed after four days.

50. In the two studies published in 1985 and 1986, Wehner and colleagues (Wehner *et al.* 1985; Wehner *et al.* 1986) investigated the translocation of talc in animals. As noted in the

studies, these were commissioned and funded by PCPC.[35] At the time these studies were conducted, Dr. Wehner was also a consultant with Johnson & Johnson. Wehner *et al.* (1985) first examined the ability of bone black particles to translocate from the vagina upwards into the oviducts in monkeys. Five monkeys were instilled with 0.3 ml of a 4% bone black suspension in the posterior fornix during their mid-menstrual cycle, followed by injection of oxytocin intra-muscularly. Animals were sacrificed either one hour (n=3) or 72 hours (n=2) after vaginal instillation was performed. The authors stated that they did not believe any translocation had occurred but could not rule it out with certainty. Thus, two additional monkeys were administered radiolabeled talc in a pilot study (single doses of talc) and the animals were sacrificed after 72 hours. Again, the authors reported no translocation occurred in the animals. In a follow-up study, Wehner *et al.* (1986) again examined talc migration in monkeys. Unlike the monkey studies of Gardner *et al.* (1981) and the studies in rats and rabbits discussed above, this was the only animal study published up to this time where the authors reported no translocation of talc to the oviducts. Six monkeys were used by Wehner and colleagues in this *in vivo* study where low doses of radiolabeled talc (125 mg) were instilled into the vagina of the monkeys under sedation, 30 times over 45 days. In three of six monkeys tested, there was no talc found and the investigators believed it may have been due to menstrual flow that had occurred in the monkeys at different times during the experiment. The authors also stated that their results differed from those of an earlier group (Gardner *et al.* 1981) and suggested the differences may have been due to use of much lower doses of talc, different materials, and longer sedation times. The data by this group were inconsistent with other animal data but most importantly they were inconsistent with the human data which is the most relevant data in terms of the issue of movement of particles in women.

51. By the 1990's the issue of migration of substances upwards in the female reproductive tract was discussed in the medical literature in review articles, indicative of the general acceptance in the scientific community of the ability of particles to migrate up the female reproductive tract. In one review (Wright *et al.* 1996), the authors began by stating: "*Dusting powders are used…**These powders can gain access to the abdominal cavity through the vagina** and during surgery, and they have caused numerous complications that have serious, life-threatening consequences." [**emphasis** added]* In the discussion section of this paper the authors

[35] The PCPC was known at the time as the CTFA (see footnote on page 329 of Wehner *et al.* (1986)).

pointed out that the known toxicity of talc in human tissue and *"the ability of the female genital tract to transport particles to the abdominal cavity"* should lead to physicians discouraging their patients to use talcum powder in the perineal area or when dusting diaphragms.

52. In a 1996 article, scientists directly addressed the issue of perineal talc usage and ovarian talc particle burden (Heller *et al.* 1996). The scientists examined ovarian tissue from 24 women undergoing ovary removal; the patients were interviewed regarding talc usage. Twelve women reported frequent perineal talc applications, while twelve reported no use, although diapering history was not available in all women (the authors considered baby powder use during diapering as a potential source of talc powder exposure in the past). The authors conclusions were stated in their abstract as follows: *"The detection of talc in all ovaries demonstrates that it can reach the upper genital tract. Widespread exposure to talc during diapering may contribute to the ubiquitous presence of talc in ovarian tissue."* This paper has been criticized based on the issue of potential laboratory contamination that could have contributed to the results, as well as the fact that women reporting no perineal use had talc detected in ovarian tissue. Regardless of these limitations, however, the results showing higher overall particles counts in women reporting perineal application of talc are nevertheless consistent with the ability of talc particles to migrate up the female reproductive tract. More importantly, this study is but a small piece of the overall evidence that supports the ability of talc to migrate from the vagina to the ovaries.

53. In a series of studies conducted in the 1990's and into the 2000's, Dr. Kunz reported on the importance of the uterine peristaltic pump to the ability of sperm to be rapidly transported through the female reproductive tract (Kunz *et al.* 1996; Kunz *et al.* 1997; Kunz and Leyendecker, 2002; Kunz *et al.* 2007). In the initial studies, Kunz and colleagues (Kunz *et al.* 1996) used hysterosalpingoscintigraphy as a tool to examine transport of particles up the reproductive tract in women. Technetium-labelled albumin spheres from 5 to 40 microns (a size similar to talc particles found in body powders) were instilled at the posterior vaginal fornix (upper vaginal area) and the path of the spheres was followed. The authors reported immediate movement of the spheres up the tract, with spheres detected in the fallopian tubes within minutes. The movement was greatest during the follicular phase of a woman's cycle. The authors stated: *"Furthermore, our studies with inert particles suggest that this directed ascension is not a property of the spermatozoa and is thus*

not provided by mechanisms such as chemotaxis, ***but rather constitutes a specific utero-tubal function controlled by the dominant follicle in that the uterine myometrium with its specific architecture (Goerttler, 1930) is activated and contracts in a manner providing this directed transport****." [****emphasis*** *added]* In other words, the motility of the sperm was not needed for transport to occur. In a 2007 study (Kunz *et al.* 2007), Dr. Kunz used methods similar to ones employed in his 1996 study. He again showed that technetium-labelled albumin spheres from 5 to 40 microns (a size similar to talc particles found in body powders) that had been instilled into the vagina were transported up the female genital tract, both with and without oxytocin use. The paper describes the now well-established ability of small particles to migrate upwards, with greatest movement occurring during the follicular phase of a woman's cycle (see reviews of the role of the uterine peristaltic pump, *e.g.*, Kunz *et al.* 1997; Kunz and Leyendecker, 2002; Zervomanolakis *et al.* 2007).

54. Two additional studies were identified in the scientific literature that related to particle migration in women (Kadanali *et al.* 2001; Sjosten *et al.* 2004). Kadanali and colleagues (2001) discussed upwards transport in the genital tract in women. Although the focus of their paper was on movement of sperm in women with IUD devices in place, one group of women were treated by intra-vaginal instillation of albumin microspheres (referencing use of the method of Iturralde and Venter) instead of sperm. The microspheres were from 10 to 90 microns in size (also in the size range of talc particles found in body powders). The authors reported that while active sperm migration was greatly inhibited (9 of 14 subjects, 65%) in the presence of an IUD, passive transport of the particles was not affected (10 of 10 subjects, 100%) in IUD-bearing women. These data provided additional support for the migration of particles upwards into the fallopian tubes of women, even women with an IUD device implanted. With respect to powder migration specifically, Sjösten and colleagues (2004) reported results of a study in humans to confirm migration that had been observed in an animal model. In the study, one group of women (n=12) underwent a gynecological exam with powdered gloves the day before an abdominal hysterectomy and another group was examined with powdered gloves four days before surgery (n=12). Two control groups were examined with powder-free gloves (n=12 or n=14). Cell smears were taken from the peritoneal fluid and during the operation further smears were taken from the fallopian tubes, uterine cavity and cervical canal. The authors reported that retrograde migration of starch

particles had occurred in humans after examination with powdered gloves. The authors concluded: *"Consequently, powder or any other potentially harmful substance that can migrate from the vagina should be avoided."*

55. Considered together, these studies conducted in both humans and in animals demonstrate the ability of particles to be transported upwards against gravity in the female reproductive tract. These studies provide support for the FDA statement in 2014 that the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity "*is indisputable*". More importantly, studies going as far back as the 1960's provided direct evidence for the potential of particles to migrate from the vagina to the ovaries in humans. At least in 2004, Imerys was acknowledging that *"compelling evidence"* for migration had been published (IMERYS288328-330).

56. Before leaving this discussion of talc migration, it is important to point out that in its review of the issue of talc migration in the genital tract of women, the CIR panel mentions many of the same studies described above; however, there is no mention of eight additional human studies and reviews of the issue (*i.e.*, Parmley and Woodruff, 1974; McCalley *et al.* 1985; Wright *et al.* 1996; Kunz *et al.* 1996; Kunz *et al.* 1997, Kadanali *et al.* 2001; Kunz and Leyendecker, 2002; Kunz *et al.* 2007). All eight of these papers were available by the time of the CIR review. Therefore, it appears the CIR panel failed to account for all the studies that informed on the issue of migration of particles, such as talc, upwards through the reproductive tract. This omission is particularly important given the fact that the CIR panel stated the following with respect to the epidemiological studies and how that data was considered:

> *"The Panel stated that causation would depend on the migration of talc from the perineum to the ovaries. There is no conclusive explanation for the presence of talc in the ovaries reported in some studies. However, the Panel agreed that there is no known physiological mechanism by which talc can plausibly migrate from the perineum to the ovaries." [see page 23 of the CIR Final Report dated April 12, 2013]*

The CIR process (discussed in detail below) was limited by the omission of a series of human studies and review papers directly relevant to the issue of talc particle migration. As a result, I

agree with the FDA's conclusions on this issue and assign little weight to the conclusions reached by the CIR panel concerning talc migration.

VI. Talc and Cancer

57. In this case, the toxicity of concern for talcum powder products exposure in humans is cancer. The specific risk issue for this case is exposure to powdered talc products through perineal or genital application, as well as inhalation exposure, leading to migration of talc internally, resulting in ovarian cancer. The issue of talc and cancer risk in humans has been recognized for decades (see papers discussed in reviews such as EPA, 1992; IARC, 2010). Although ovarian cancer is the focus of the current case, other forms of cancer have also been linked to talc exposure (*i.e.*, lung cancer with inhalation exposure to talc; IARC, 2010) To determine whether there is a reasonable basis to conclude there may be a health hazard associated with talcum powder products, it is important to review the totality of the evidence to determine whether there is scientific support. Therefore, I have considered available *in vitro* and *in vivo* toxicology data, mechanistic data, epidemiological studies, and other evidence. In reviewing the evidence, I employed the methodology as discussed earlier in my report (see paragraphs 6, 11, 12, and 13).

58. There is a body of mechanistic data that also needs to be considered when looking at the issue of talcum powder products and risks to human health. It is important to remember that administration of even a single dose of talc in animals has been shown to produce adverse effects locally, at the site of exposure, that have included granulomatous reactions, cellular proliferation, and adhesions (as reviewed by EPA, 1992). Thus, evidence shows that talc exposure induces local tissue responses that are adverse effects, not simple adaptive effects, and those effects lead to tissue damage.

59. Talc can induce toxicity in tissues and cells through direct contact. The studies discussed above related to the ability of talc to migrate from the vagina upwards in the reproductive tract in women are important evidence that talc can arrive at sites where local tissue toxicity would be produced, such as the fallopian tubes and the ovaries. Studies looking at local tissue effects of talc would be important when examining a mechanistic basis for talc carcinogenicity in humans.

Starting in the 1980's, studies appeared in the scientific literature related to understanding the local tissue effects of talc. In an early study, the cytotoxicity of seven different respirable talc products (expected to be of high purity) provided to researchers by the PCPC were studied (Davies *et al.* 1983). Specifically, the fibrogenic potential of talc was investigated through use of a cell bioassay (macrophage toxicity) using murine peritoneal macrophages. All seven talc samples tested were found to be cytotoxic and the authors stated they *"would be expected to be fibrogenic in vivo"*. In another study (Hamilton *et al.* 1984), direct exposure to what was claimed to be asbestos-free talc (via single intra-bursal injection) on the surface of the ovaries of rats was associated with adverse effects including *"focal areas of papillary change"* on the surface epithelium of the ovaries, often discussed as pre-neoplastic lesions; thus, talc was toxic to ovarian tissue in mammals. Beck and colleagues (1987) examined the local tissue toxicity of talc dust (stated to be asbestos-free and granite-free dust), as well as other mineral dusts,[36] *in vivo* in animals (hamsters) following a single intra-tracheal instillation of a dust into lung tissue. The experiments examined the dose-response relationship (0.15, 0.75 and 3.75 mg talc/100 g body weight) and the time course (1 to 14 days post-exposure) of the effects of dust exposure in lung tissue. The authors stated: *"One day after exposure, both talc and granite dust resulted in elevated enzyme levels and pulmonary cell numbers in BAL [bronchial alveolar lavage fluid]. Macrophage phagocytosis was also inhibited. Based on results from earlier studies, response levels were either intermediate between nontoxic iron oxide and toxic a-quartz or comparable with n-quartz. The response to granite dust diminished fairly rapidly over time. By contrast, after talc exposure, there was a more persistent elevation in enzyme levels, and macrophage phagocytosis remained depressed. These results indicate that when a similar mass was deposited in the lungs,* ***talc caused more lung injury than did granite****." [****emphasis*** *added]* In another study (Radic *et al.* 1988), talc was shown to suppress immune system function in rats injected subcutaneously with talc. Talc induced granulomatous reactions in the animals, and spleen cells from talc-treated rats suppressed the immune response. Each of these studies provided evidence that talc is toxic to cells and tissues that are contacted with talc dusts/particles, including ovarian tissue.

60. In 1993, the results of chronic GLP-quality studies conducted from 1984-1986 in rats and mice were reported (NTP, 1993; P-0832 was the draft report). In these studies, using

[36] Granite dust was tested in this study as well.

standard study methods of the time, the potential for talc (stated to be asbestos-free) to produce cancer following inhalation was studied. The study rationale was stated as follows: *"Talc was nominated by NIOSH in 1978 for testing by NTP because of the paucity of adequate information on its carcinogenicity and because of widespread human exposure. The inhalation route was chosen because it is the most common route for human exposure."* Although earlier studies had investigated the cancer potential of talc (see review in IARC, 1987), limitations in study design affected their utility for human health risk assessment (*i.e.*, less than lifetime exposures, small group sizes, *etc.*). An important feature of this study was the interim sacrifices performed in both rats and mice in all three exposure groups of both sexes (see Table 5 and Table 11 of NTP, 1993). This meant that the evolution of lung lesions was examined in the animals, allowing for identification of a potential mechanism for lesions that developed in lung tissue. The study authors concluded:

> *"Under the conditions of these inhalation studies, there was some evidence of carcinogenic activity of talc in male F344/N rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland. There was clear evidence of carcinogenic activity of talc in female F344/N rats based on increased incidences of alveolar bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland."*

This information alone is significant for human health risk assessment; however, the findings from the interim sacrifices in both rats and mice were extremely useful in terms of identifying a mechanism for lung tumors in rats and mice. The text from the study is quoted below as it provides important support for a mechanism for talc-induced carcinogenesis.

> *"Although the inflammatory response was basically similar in rats and mice, there were important species differences. The lesions in rats were generally more extensive and more severe than those in mice at similar exposure concentrations. In rats, foreign body giant cells were occasionally observed and some of the alveolar macrophages developed the morphological characteristics of epithelioid macrophages. More importantly, the* ***inflammatory lesions in rats were accompanied by interstitial fibrosis, hyperplasia of alveolar type I1 epithelial cells, and, infrequently, squamous metaplasia of the alveolar epithelium****." [****emphasis*** *added; see page 51 of NTP 1993]*

> *"A **potential mechanism** for the development of pulmonary neoplasms associated with insoluble particulate substances is that **the prolonged stimulus for cell replication, due not only to cell injury but to the release of mitogenic growth factors from alveolar macrophages, provides a favorable environment for the promotion and progression of spontaneously initiated cells.** The interim evaluations in the NTP talc study clearly demonstrate **a progressive impairment of homeostatic growth regulation in the areas of chronic inflammation and fibrosis associated with talc deposition in rats**. Hyperplasia of the alveolar epithelium was evident at 6 months and became more extensive and severe with duration of exposure. Not only were there increased numbers of cells (hyperplasia), but some cells assumed morphologic features atypical of regenerating or differentiated type I1 cells (epithelial dysplasia). The altered or dysplastic epithelium was particularly evident in areas of fibrosis. The squamous metaplasia observed in female rats also represents altered differentiation of populations of alveolar epithelial cells and is notable in light of the development of squamous cysts and squamous cell carcinomas." [**emphasis** added; see pages 54-55 of NTP, 1993]*

Thus, these data from interim sacrifices in rats and mice provided an important signal for human safety. The 1993 NTP study has been criticized and conclusions reached by the original authors have been questioned (*i.e.*, Carr, 1995; CIR, 2013). Yet, even with its limitations, the study provides important information on talc toxicity that is relevant to assessing the risks of cancer in humans. In fact, scientists that initially reviewed the study supported the use of the data for listing of talc in NTP's Report on Carcinogens (RoC; discussed in more detail below). It also should be noted that based on an inhalation route of exposure in rats and mice that was employed in the studies (NTP, 1993), the studies would not be expected to produce ovarian tumors in rats or mice given the route of exposure that would severely limit any perineal exposure to talc. Moreover, unlike humans, the ovaries of rats and mice are completely covered by a bursal sac, making direct access to ovarian tissue unlikely when exposure is assumed to be due to vaginal penetration and migration to the ovaries.

61. In more recent studies, the biologic basis of effects in cells and tissues associated with exposure to talc that could be linked to carcinogenesis were evaluated. In one study, (Buz'Zard and Lau, 2007) normal ovarian cells in culture were treated with increasing concentrations of talc in solution, either with or without the presence of a chemotherapeutic agent that has been shown to have anti-cancer activity (*i.e.*, inhibits oxidative damage in cells, induces apoptosis of cancer cells). The authors reported that talc treatment increased generation of reactive oxygen species in ovarian cells and induced neoplastic transformation. In another study looking at cellular changes associated with mineral exposure, Shukla and colleagues (2009) examined mineral pathogenicity of four different particles, including asbestos and non-fibrous talc. Human lung mesothelial cells and human ovarian epithelial cells in culture were employed. Both types of cells were exposed to increasing concentrations of asbestos, talc, titanium oxide and glass beads. The asbestos was identified as crocidolite asbestos with a mean size of 7.4 µm and had greater than 3:1 length to width ratio. The talc was stated to have a mean size of 1.1 µm and was stated to occur as *"platy particles that were uniform in appearance"* (by field emission scanning electron microscopy). The results of most interest in terms of mechanism of action that relates to the potential to produce a carcinogenic response in tissue included the cell viability data and the changes in gene expression induced by exposure to asbestos and talc. As expected, asbestos fibers were toxic to human cells, both lung and ovarian cells; asbestos is a known human carcinogen. The authors reported that the lung cells were more sensitive to the toxic effects of asbestos; however, testing of only two doses of asbestos limit the conclusions that can be drawn about differences between cells. In the case of talc, lung cell viability was decreased in a dose-dependent manner; decreased viability was reported at talc doses of 15 and 20 µg/m^2. When two lower doses of talc, 1 and 5 µg/m^2, were tested in ovarian cells, there was no effect on cell viability. Gene expression changes in lung mesothelial cells also were examined, and exposure to asbestos for up to 24 hours was associated with significant effects on gene expression. The authors reported that fewer gene expression changes occurred in ovarian cells exposed to asbestos. They also reported that fewer gene expression changes were observed in lung cells following exposure to talc at a dose of less than 5 µg/m^2 for up to 8 hours, and no significant changes in ovarian cell gene expression were observed with talc exposure. However, when the list of genes whose expression was affected by asbestos and talc was examined, it is seen that some of the genes affected are involved in cellular processes that relate to oxidative stress and inflammation. The authors of this

study failed to test talc with the same rigor that asbestos was tested in their study, limiting the data collected on talc itself. Nevertheless, the study did reveal statistically significant increases in *ATF3* and IL8 expression by asbestos and non-fibrous talc at certain concentrations. The data collected with asbestos exposure supports known toxicity of induction of oxidative stress as a mechanism underlying carcinogenesis (IARC, 2012).

62. The same research group (Hillegass *et al.* 2010) further examined the pathogenicity of asbestos as compared to other particles, including talc. The authors reported that their analysis of microarray data confirmed that lung cells were *"more responsive than ovarian cells to crocidolite asbestos or non-fibrous talc, and that crocidolite asbestos elicited greater responses in both cell types when compared to non-fibrous talc"*. As before, however, the group failed to test talc across a range of doses that would be necessary to examine its effects in these assays, using only doses that were equivalent to asbestos even though it was known that the crocidolite asbestos would be expected to be more potent in terms of biological reactivity than talc. The authors did, however, report that *"the pathogenesis of asbestos-associated diseases is most commonly associated with a persistent inflammatory response initiated by ROS, growth factors, and/ or various pro-inflammatory factors such as cytokines or chemokines"*. Therefore, this paper provided further evidence supporting the mechanism of inflammation and generation of reactive oxygen species as important to the tissue responses induced with exposure to particles that would include both asbestos and talc.

63. In a more recent study (Shim *et al.* 2015), the effect of talc to induce oxidative stress *in vivo* following administration of talc was examined. Rats were exposed to talc via whole-body inhalation at concentrations of 0, 5, 50 and 100 mg/m^3, six hours per day, five days per week, for four weeks. It should be remembered that in a GLP-quality lifetime study in rodents (NTP, 1993), rats were exposed to talc via whole-body inhalation at doses of 0, 6 and 18 mg/m^3, six hours per day, five days per week, and there was clear evidence of talc-induced chronic inflammation, reparative processes and cellular proliferation (as evidenced by lung pathological changes observed at interim sacrifices of 6, 11, and 18 months). This shorter-term study in rats by Shim *et al.* (2015) focused on understanding the role of oxidative stress in the tissue responses to talc, a general mechanism that has been linked to chronic inflammation and cancer, including ovarian

cancer (*e.g.,* Saed *et al.* 2017; Saed *et al.* 2018; Fernandes *et al.* 2015; Landskron *et al.* 2014; Kamp *et al.* 2011; Grivennikov *et al.* 2010; Lu *et al.* 2006; Rakoff-Nahoum, 2006; Senthil *et al.* 2004; Ness *et al.* 2000). The authors reported that inhalation of talc for four weeks was associated with macrophage aggregation and oxidative damage in the lung, including significantly increased expression of superoxide dismutase 2 (SOD 2), a biological indicator of oxidative damage.

64. In two other recent studies, the effects of talc exposure to induce oxidative stress in ovarian cancer cells has been investigated (Fletcher *et al.* 2018; Fletcher and Saed, 2018; both studies are available as abstracts only at this time). In the first study that was presented at a scientific meeting in March of 2018, the researchers reported on the ability of talc to affect markers of oxidative stress in ovarian cancer cells in culture (Fletcher *et al.* 2018). Both normal ovarian epithelial cells and cancerous ovarian epithelial cells were incubated with talc at concentrations of 0, 200 and 500 µg/ml for 24, 48 and 72 hours. The talc was purchased from Sigma Aldrich.[37] There was a marked increase in mRNA levels of pro-oxidant enzymes in both ovarian cell lines as compared to controls (untreated), and a marked decrease in mRNA levels of anti-oxidant enzymes in both cell lines as compared to controls (untreated cells). These changes, indicative of a pro-oxidant state in the cells (oxidative stress), were reported to occur as early as 24 hours after exposure. The authors concluded: *"This is the first report to show that talcum powder induces biological effect by further enhancing the redox state in both normal ovarian epithelial cells as well as ovarian cancer cells. The results of this study will provide a molecular basis to previous reports that link genital use of talcum powder to increased risk of epithelial ovarian cancer."* In the second study by this same laboratory (Fletcher and Saed, 2018), additional investigation of the effects of talcum powder on ovarian cancer cells was performed. The objective was to determine the effects of talcum powder on levels of the cancer antigen, CA-125, in both normal ovarian cells and ovarian cancer cells. The authors state that levels of CA-125 are elevated in more than 80% of women with advanced ovarian cancer and 50% of women with early stage cancers. Ovarian cells were exposed to 0 or 1000 µg/ml talc for 72 hours and levels of CA-125 were determined by ELISA methods. The authors report that there were increases in CA-125 levels in response to talc treatment in both normal and cancerous cells. The authors concluded: *"Talcum powder induces a biological effect by further enhancing CA-125 levels in ovarian cancer cells as well as in normal*

[37] The Sigma Aldrich website indicates that the talc sold is pharmaceutical grade talc.

ovarian epithelial cells. This will provide a molecular basis to previous reports that link genital use of talcum powder to increased risk of epithelial cancer." Moreover, in a recent review of the pathogenesis of ovarian cancer by Dr. Saed and colleagues (Saed *et al.* 2018), the importance of oxidative stress to pathogenesis and prognosis of ovarian cancer is discussed. The effects of talc in cells and tissues that are linked to oxidative stress provide additional insight into the molecular basis of talc-induced ovarian cancer in humans.

65. Talc body powders manufactured and sold by Imerys and Johnson & Johnson were a mixture of compounds, many of which have toxic properties. There is consistent evidence linking talc as well as the other components of talc with initiation of inflammation at the local site of exposure (discussed above), as well as evidence that talc induces biologic effects that result in pre-cancerous lesions (NTP, 1993). Inflammation is a well-studied mechanism of carcinogenesis (*e.g.*, Fernandes *et al.* 2015; Grivvennikov *et al.* 2010; Fleming *et al.* 2006; Lu *et al.* 2006; Rakoff-Nahoum, S. 2006; Ness and Cottreau, 1999). As discussed in a recent review of the topic of inflammation and cancer (Grivennikov *et al*. 2010), there are several basic facts about inflammation and cancer that include the following: (1) chronic inflammation increases cancer risk; (2) subclinical, often undetectable inflammation may be as important in increasing cancer risk; (3) various types of immune and inflammatory cells are frequently present within tumors; (4) immune cells affect malignant cells through production of cytokines, chemokines, growth factors, prostaglandins, and reactive oxygen and nitrogen species; (5) inflammation impacts every single step of tumorigenesis, from initiation through tumor promotion, all the way to metastatic progression; (6) in developing tumors anti-tumorigenic and pro-tumorigenic immune and inflammatory mechanisms coexist, but if the tumor is not rejected, the pro-tumorigenic effect dominates; (7) signaling pathways that mediate the pro-tumorigenic effects of inflammation are often subject to a feed-forward loop; and (8) certain immune and inflammatory components may be dispensable during one stage of tumorigenesis but absolutely critical in another stage. Therefore, in the case of talc, even if tissue samples from ovarian tumors fail to exhibit signs of active chronic inflammation, an inflammatory role for talc is not ruled out. Instead, the role of talc in inducing the tumorigenic response could be linked to earlier stages of cancer progression.

66. With respect to inflammation and ovarian cancer specifically, a recent prospective epidemiological study performed by investigators at the National Institutes of Health has linked specific pro-inflammatory markers in blood with the presence of ovarian cancer in women (Trabert *et al.* 2014); the authors suggest that these pro-inflammatory mechanisms may be linked to the increased risk of ovarian cancer seen in women exposed to compounds such as talc and asbestos. Other supporting evidence for a link of inflammation with carcinogenesis following talc exposure in women are the studies that have shown that talc exposure can induce oxidative stress in cells (discussed above). Therefore, there are multiple plausible mechanisms that may be related to the cancer hazard posed by perineal talc body powder exposure in women. Additionally, the fact that talc can act as a cancer promoter is also relevant (Stenback *et al.* 1986). Finally, it is important to note that the link of talc with inflammatory processes is an underlying toxic insult that can lead to cancer. This mechanism is consistent with mechanisms linked to other particles that induce cancer (*i.e.*, asbestos and silica; Moller *et al.* 2010, Moller *et al.* 2013; IARC, 1987; IARC, 2010). It is also important to realize that there is latency associated with cancer pathogenesis which would also apply in the case of talc.

67. When considered together, the scientific literature on the biological effects of talc, as well as asbestos and other constituents routinely found in talc (discussed above), provide sufficient evidence to show that these chemicals produce cellular changes that have been linked to carcinogenesis and that the biological mechanism for carcinogenesis (ovarian and/or lung) following exposure to talcum powder products likely involves induction of a chronic inflammatory response. A review of the IARC monographs for talcum powder product constituents, such as asbestiform talc and non-asbestiform talc, nickel, cobalt, and chromium, reveals similarities in the biological effects that are discussed as underlying the carcinogenic potential of the individual compounds. Moreover, available evidence indicates that local exposure to talc particles is likely involved, where "local exposure" means exposure at or near the site of injury, in this case exposure of the ovary and ovarian cancer. It is important to realize as well that in the case of almost any human drug used to treat a disease or symptoms of some condition, the exact molecular mechanism by which the drug produces its effects also are not known. Thus, not knowing every detail about the molecular mechanism underlying talcum powder products and carcinogenesis does not mean that the available data fail to provide support for a likely mechanism. In fact, we know some

important things about talc, information that supports the biologic plausibility of the relationship between talc exposure and human cancer. This mechanistic data provides highly plausible biological support for the signal for human cancer risk identified from the epidemiological (discussed below) and animal data.

68. When considered together with general principles of toxicology, the available data relating to mechanism of carcinogenicity of talcum powder products, where the body powders are a mixture of compounds with carcinogenic hazard, indicate that the various compounds in talcum powder products would be expected to produce at least an additive effect on the risk of cancer based on their ability to induce similar biological responses that underly carcinogenesis (Eaton, D.L. and S.G. Gilbert. 2013. Principles of toxicology. In: *Casarett & Doull's Toxicology: The Basic Science of Poisons, 8th edition*. Klaassen, C.D. (ed.). McGraw-Hill: New York: NY. Chapter 2, pp. 19-20; EPA, 2000). The likely mechanism for cancer is related to the similar cellular events that have been linked to carcinogenesis in the case of the known components of talcum powder products.

69. It is well-established that there are two types of chemical carcinogens: genotoxic and non-genotoxic (Klaunig, J.E. 2013). A genotoxic carcinogen is one that is mutagenic, may be a complete carcinogen, produces tumors that exhibit a dose-response relationship with exposure, and for which there is no threshold for cancer initiation[38]. A non-genotoxic carcinogen is one that is not a direct mutagen, exhibits a threshold for tumor development, produces tumors that exhibit a dose-response relationship with exposure, may only function as a tumor promoter, does not directly damage DNA, and may exhibit species, strain and tissue specificity in response. The available evidence indicates that talc may be a non-genotoxic carcinogen, as defined here, based on the evidence showing that it is not genotoxic (in most assays), requires repeated dosing of sufficient duration for tumors to be produced, has been shown to exhibit activity as a tumor promoter for known carcinogens (*i.e.*, benzo(a)pyrene; Stenback *et al.* 1986), exhibits species and tissue specificity in tumor responses (associated with local site of exposure), and has not been shown to directly damage DNA. The available animal cancer data has not been assessed for a threshold for tumor development, but the NTP study data did indicate that the tumor response was

[38] Asbestos has been identified as a genotoxic carcinogen.

a high dose effect. Human studies, however, have indicated that ovarian cancer exhibits a dose-response in terms of being associated with an increased duration of use and frequency of use of talc-based products (*e.g.*, Cramer *et al.* 1999; Terry *et al.* 2013; Wu 2015; Schildkraut *et al.* 2016; Berge *et al.* 2018; Penninkilampi and Eslick 2018). Therefore, the available evidence indicates that talc's plausible mechanism of action to induce cancer would be through non-genotoxic (indirect) pathways.

70. I also would like to point out that talc powder is used clinically to cause an acute inflammatory response in a procedure known as pleurodesis. This procedure is designed to cause the two layers of the lung pleura, parietal and visceral layers, to stick together so that the space between the layers is filled with scar tissue. Typically, only a few ounces of fluid would be found between the parietal and visceral pleural membranes, but the fluid can build up to as much as a few liters and is known as a pleural effusion. Both mechanical and chemical means are used to initiate the lung scarring that is needed to treat these effusions. In the case of chemical pleurodesis, a substance such as talc powder can be placed into the chest cavity near the lungs to produce an acute inflammatory response that leads to scarring. The size of the talc particles used in the procedure are important; severe inflammatory effects were more likely when a talc powder with smaller particles, about 50% less than 10 µm, was employed (Arellano-Orden *et al.* 2013). It is important to note that typical talcum powder products, including those manufactured and sold by Imerys and Johnson & Johnson, contain mostly small particles, less than 10 µm (Zazenski *et al.* 1995; JNJ000326966; IMERYS095244; IMERYS120564-565). Thus, the pleurodesis literature provide further support for inflammation as a known tissue response to talc, even though the type of inflammatory response produced in pleurodesis procedures is acute, not a chronic response as is characteristic of carcinogenesis.

71. As discussed above in paragraph 33, an increased human cancer risk has been linked to components of talcum powder products, such as asbestos. By the 1930's, evidence was available linking asbestos exposure with lung disease, including lung cancer; by the mid 1950's, the majority of scientists believed that asbestos could cause lung cancer, and likely other forms of cancer, in humans (Doll, 1955); and by the 1960's, evidence had accumulated linking asbestos exposure with ovarian cancer, with some studies reporting an increased incidence in women

exposed to asbestos. Beginning in the 1970's, the issue of ovarian cancer in women began to be discussed with respect to talcum powder product exposure (Henderson *et al.* 1971; Henderson *et al.* 1979). Since that time, the study of, evidence for, and discussion of, a cause and effect relationship between talc exposure and human ovarian cancer risk has continued to develop in light of the totality of the data (*e.g.*, Cramer *et al*. 1982; Hartge *et al.* 1983; Natow, 1986; Whittemore *et al.* 1988; Booth *et al.* 1989; Harlow and Weiss, 1989; Harlow *et al.* 1992; Chen *et al.* 1992; Rosenblatt *et al.* 1992; Tzonou *et al*. 1993; Cramer and Xu, 1995; Purdie *et al.* 1995; Shushan *et al.* 1996; Chang and Risch, 1997; Cook *et al.* 1997; Green *et al*. 1997; Daly and Obrams, 1988; Eltabbakh *et al*. 1998; Godard *et al.* 1998; Cramer, 1999; Wong *et al.* 1999; Ness *et al.* 2000; Langseth and Kjaerheim, 2004; Mills *et al*. 2004; Jordan *et al.* 2007; Merritt *et al.* 2008; Wu *et al.* 2009; Rosenblatt *et al.* 2011; Kurta *et al*. 2012; Terry *et al.* 2013; Houghton *et al.* 2014; Wu *et al.* 2015; Schildkraut *et al.* 2016; Berge *et al.* 2018; Penninkilampi and Eslick, 2018). A review of these studies as a whole shows that exposure to talc by routine genital application is reported to increase the risk of ovarian cancer in women by about 30% (*e.g.*, Cramer *et al.* 1982; Whittemore *et al.* 1988; Booth *et al*. 1989; Harlow and Weiss, 1989; Harlow *et al.* 1992; Rosenblatt *et al*. 1992; Purdie *et al*. 1995; Shushan *et al.* 1996; Chang and Risch, 1997; Cook *et al.* 1997; Cramer *et al.* 1999; Gertig *et al.* 2000; Ness *et al.* 2000; Mills *et al.* 2004; Merritt *et al.* 2008; Wu *et al.* 2009; Rosenblatt *et al.* 2011; Kurta *et al*. 2012; Terry *et al.* 2013; Schildkraut *et al.* 2016; Berge *et al.* 2018; Penninkilampi and Eslick, 2018). Not all studies identified in the published scientific literature have reported a statistically significant increased risk of ovarian cancer following talc exposure in women (*e.g.*, Hartge *et al.*, 1983; Chen *et al.* 1992; Tzonou *et al.* 1993; Godard *et al.* 1998; Wong *et al.* 1999; Langseth and Kjaerheim, 2004; Houghton *et al.* 2014). With such a large group of epidemiological studies, with varying designs, sizes of the populations studied, and varying measures of exposure, it is not surprising that there are studies that show both an increase in risk as well as those that failed to report such results. Yet, in the large group of studies (22 studies) reporting statistically significant findings, the increased risk is consistently seen to be in the range of 30%. Even in the studies that reported non-statistically significant findings, there often was a trend towards an increased risk in women who used talcum powder products. The human epidemiological data related to talcum powder product use and cancer risk in women, when considered in conjunction with the biological data on talc migration, as well as cellular and animal

data regarding inflammation and talc's induction of carcinogenicity, supports the conclusion that use of talcum powder products may pose a health hazard to women.

72. As a part of my risk assessment, I also considered whether there is a dose response. In the current case where the chemical of concern is a particle, and the route of exposure of concern is external application of a powder that then migrates internally, and the powder itself is a mixture of a variety of compounds some of which are known human carcinogens, the concept of dose is more complex. The human studies do not provide a measure of a single dose in terms that are typical of the cellular (*in vitro*) or animal studies, *i.e.,* mg talc per kg body weight, or mg talc per m^3 inhaled air, or mg talc per ml of solution. In the case of the talc database, dose for human is expressed terms of frequency and duration of exposure. It is a general principle of pharmacology and toxicology that just as the likelihood of a response increases with dose, the likelihood of a response increases with longer term use, and more frequent use (Eaton and Gilbert, 2013). The available *in vitro* and animal study data show that there is a dose-response relationship for talc toxicity (*e.g.,* EPA, 1992; NTP, 1993; IARC, 2010; Buz'Zard and Lau, 2007; Shukla *et al.* 2009; Shim *et al.* 2015). The animal cancer data, when considered in conjunction with the cellular data, indicate that talc is a carcinogen and there likely is a dose-response threshold for tumor development in rodents (NTP, 1993). There are several human studies that provide evidence of a dose-response relationship for talc exposure and ovarian cancer in women (see paragraph 69; Cramer *et al.* 1999; Terry *et al.* 2013; Schildkraut *et al.* 2016; Cramer *et al.* 2016; Berge *et al.* 2018; Penninkilampi and Eslick, 2018). Therefore, there are sufficient scientific data supporting the existence of a dose-response relationship for genital talc use and an increased risk of ovarian cancer.

73. In 1978, the U.S. Congress amended Section 301(b)(4) of the Public Health Service Act, to require the Secretary of the Department of Health and Human Services (DHHS) to publish an annual report that contains a list of all substances that *"are known to be human carcinogens or may reasonably be anticipated to be human carcinogens and to which a significant number of persons residing in the United States are exposed"*.[39] The process of producing the list, known as the Report on Carcinogens, or RoC, results from periodic meetings and is a process managed by

[39] https://ntp.niehs.nih.gov/pubhealth/roc/history/index.htm

the NTP on behalf of DHHS. There have been 13 RoC processes to date, the 13th RoC being published in 2014. Talc was considered as part of the 10th and 12th RoC processes. The 10th RoC meeting where talc was discussed was held in 2000, while the 12th RoC meeting on talc was held in 2005. The 10th RoC deferred action to list talc as a carcinogen, citing a need for additional information; the 12th RoC also deferred action to list talc. It is important to note that the NTP RoC nominated talc for consideration for listing in the 10th RoC based on a review of the available data by a body of scientists without input from industry, and without any direct interaction with other industry groups or representatives with a conflict of interest, consistent with the procedures set forth by IARC (IARC, 2006). Johnson & Johnson, Imerys, and PCPC influenced the 10th RoC process as I discuss later in paragraph 96. It is also important to note that a review of the minutes of the 10th RoC indicates that even though the only public comments made to the panel were from industry representatives, many of the reviewers supported listing non-asbestiform talc as reasonably anticipated to be a human carcinogen (IMERYS 039060 through 085).

74. In 2010, the International Agency for Research on Cancer (IARC) Working Group published its assessment of the carcinogenic potential of non-asbestiform talc. The review of talc had occurred in 2006 and included only those papers available up to 2006. It is important to note here that the IARC review process is not open for public comment and all conclusions reflect the consensus decisions made by global experts in their field and without influence from industry. Additionally, this review occurred after the NTP talc reviews had been completed. Unlike the NTP RoC reviews, the IARC panel was able to reach a consensus regarding the cancer risks posed by talc. The IARC panel concluded that perineal use of non-asbestiform talcum powder products was *"possibly carcinogenic to humans"* (a Group 2B classification) and inhalation of non-asbestiform talc was *"not classifiable as to its carcinogenicity"* (a Group 3 classification). This finding provided additional evidence for the weight-of-the evidence assessment I performed. It should be noted that the 2006 IARC panel did not have access to the reports of Terry *et al.* (2013), Wu *et al.* 2009 and 2015, Schildkraut *et al.* (2016), Berge *et al.* 2018, and Penninkilampi and Eslick, 2018). See also paragraph 71. These additional studies provide further evidence of the link of talc exposure in women and an increased risk of ovarian cancer. Terry *et al.* (2013) performed the largest meta-analysis to date with the talc database. The authors reported that genital use of talcum powder products significantly increased the risk of all types of ovarian cancer. The paper by

Schildkraut *et al.* (2016) provided support for the existence of a dose-response relationship between talc use and increased risk of ovarian cancer in women. Berge *et al.* (2018) reported a statistically significant increased risk of serous carcinoma of the ovary, as well as the identification of a dose-response relationship (increased duration of use). Penninkilampi and Eslick (2018) performed another meta-analysis of the studies in women exposed to talc through perineal dusting with talc body powders and reported that *"there is a consistent association between perineal talc use and ovarian cancer"*. These additional studies add to the weight of evidence that genital use of talcum powder products may be a health hazard.

75. Therefore, the weight-of-the-evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women. This conclusion is supported by data that includes, but is not limited to the following: (1) the known toxic effects of talc and the other components of talcum powder products; (2) studies that have identified the biologically plausible mechanisms for cancer in humans; (3) the likelihood that talc particles can reach the ovaries; (4) the existence of a dose-response relationship for toxicity including the risk of cancer; and (5) the large human database that includes studies conducted over a period of 40 years showing a consistent signal for ovarian cancer in women exposed to talcum powder products.

VII. The Role of Industry in Talcum Powder Product Safety Assessments

76. In support of my opinions, I have reviewed and considered thousands of documents related to the actions of Johnson & Johnson, Imerys, and PCPC with respect to talc and human health risks and safety assessment. The documents related to Johnson & Johnson date back into the 1950's and 1960's (*e.g.*, patents filed by the company; studies published by company employees; internal company documents). Documents related to Johnson & Johnson and the PCPC date back to the 1970's (*e.g.*, internal company documents; exhibits to depositions of company employees or corporate representatives). Documents related to Imerys and the PCPC date back to the 1990's (*e.g.*, internal company documents; exhibits to depositions of company employees or corporate representatives). The evidence shows that the defendants worked both individually and collaboratively to present a uniform position to regulators, the scientific and medical community, and consumers, that talcum powder product use did not present a risk of ovarian cancer in humans.

77. Evidence supporting Johnson & Johnson's early efforts to influence the safety information disseminated publicly about talc in the late 1970's involved the 1975 U.S. Pharmacopeia (USP) listing for talc. Based on their efforts, the USP listing was changed in 1980 to omit the warnings *"Do not apply to open wounds"* and *"Do not inhale"* (JNJ000343613; JNJNL61_000030770; JNJ000343580; JNJ000343612; JNJ000343614; JNJ000343946; JNJ000343611; trial testimony of Dr. John Hopkins dated February 8, 2018). Johnson & Johnson relied on their assertion that there was no asbestos present in talc that met the USP standards, even though evidence shows they were aware of the presence of some level of asbestos in their products at that time (as discussed above). Moreover, by the 1970's Johnson & Johnson was aware that some scientists believed that exposure standards for asbestos should be applied to fibrous talc (JNJ000231422-428). Evidence suggests that industry knew or should have known about the significant human health risks posed by exposure to cosmetic talc body powders well before 1975. Therefore, the evidence suggest that Johnson & Johnson failed to provide accurate information to the USP regarding the issue of the presence of asbestos in talc. Moreover, in asserting that *"normal exposure to cosmetic talc presents no inhalation hazard"* (JNJNL61_000030770), the company was making statements that were not scientifically defensible given the knowledge available by 1975 concerning talc and the hazards of inhalation exposure (as discussed above). Therefore, it is my opinion that Johnson & Johnson knew or should have known that use of cosmetic talc body powders had been reported to lead to lung injury when the talc was inhaled, and to lead to adverse tissue reactions when internal tissues were exposed to talcum powder products.

78. Also, in the 1970's, documents show that Johnson & Johnson made efforts to influence the science around the issue of asbestos in talc and the link of talc with ovarian cancer (P-0055; P-0344; P-0002). The efforts included a discussion with the FDA Commissioner in 1974 where Johnson & Johnson stated: *"Our very preliminary calculation indicates that substantial asbestos can be allowed safely in a baby powder."* (P-0660). Later in the same document Johnson & Johnson states that *"if the results of any scientific studies show any questions of safety talc, Johnson & Johnson will not hesitate to take it off the market"* (P-0660). Given the fact that Johnson & Johnson was aware, or should have been aware, of the science that had accumulated by that time linking asbestos exposure with both ovarian cancer and lung cancer, the position by the company regarding the presence of any asbestos in talc body powders is inconsistent with protecting public

health when the issue involved exposure to a cosmetic product, one without any benefit. Importantly, consumers were not informed of the safety concerns regarding the presence of asbestos in talcum powder products.

79. In discussing the issues related to industry and its actions to influence the public perception of talc safety, it is important to understand the role of the CIR in cosmetic ingredient safety assessments. As already mentioned above, the CIR process is industry-funded and is administered independent of the FDA. While FDA may consider CIR conclusions, the FDA does not adopt their findings (PCPC_MDL00096145, PCPC_MDL00044971, Deposition of Dr. Linda Loretz). The panel's role is to review the available safety information for the ingredient and to come to a consensus about its safety. The CIR reports are open for public comment before they are finalized. Over the years, the CIR has reviewed and reported on over 5,000[40] ingredients, yet only 12 have been found to be "unsafe" for use.[41] The current CIR meetings involve no more than two days of discussion for ingredients and ingredient groups (talc was one ingredient amongst a multitude of ingredients in 17 ingredient groups) during which time the panel reviews the data and comes to its conclusions regarding ingredient safety (deposition testimony of Dr. Linda Loretz October 1 and 2, 2018). None of the CIR expert panel members personally review the relevant published studies; instead, the members review only the report drafted by CIR staff (see testimony of Dr. Andersen pages 3157-3158, *Echeverria v. Johnson & Johnson*). This is a much more abbreviated review process than is employed by IARC when it is making a cancer hazard assessment.[42] For example, in the IARC reviews, the Working Group, drafts the consensus document as a group while working together for seven to eight days (MDL_KELLY00002701-2702). Care is taken to ensure that detailed summaries of studies are written by relevant experts, unlike the CIR reports which are written by employees of the PCPC instead of the experts on the panel. Also unlike the IARC review process, where panel members chosen for a review are ones with specific expertise in the scientific issues that are addressed for a chemical (IARC, 2006), the CIR panel typically includes less specialized scientists; and the make up of the panel changes little from meeting to meeting even though the issues raised for individual ingredients could be very

[40] Testimony of CIR Director from 1993 to 2013, Dr. Alan Andersen dated 8/10/2017 (Echeverria v. Johnson & Johnson).
[41] https://www.cir-safety.org/cir-findings
[42] See description of the process at: http://monographs.iarc.fr/ENG/Preamble/currentbscientificintro0706.php

different (see deposition testimony of Dr. Linda Loretz in 2018). Therefore, from a scientific perspective, the IARC process involves a much more detailed scientific evaluation of the issues surrounding a cancer hazard than the issues addressed by any CIR review.

80. In deposition testimony over several days in 2018[43], corporate representatives of the PCPC provided detailed descriptions of the CIR process. The testimony of the former Director of the CIR (Dr. Andersen in Echeverria v. Johnson & Johnson dated 8/10/2018) also provided details about the CIR process, including the talc process, and the close relationship with industry. Additional information can be found in internal company documents as well (*e.g.*, P-0561; P-0595). The lack of independence of the CIR process from PCPC operations and influence by industry is apparent after review of these sources, even though a different impression is given through the CIR website. For example, at the CIR website the following is stated:

> *"The Cosmetic Ingredient Review was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America. Although funded by the Council, CIR and the review process are independent from the Council and the cosmetics industry."*

As will be discussed below with respect to the talc CIR review, the process was not independent of industry, did not include physicians with expertise in gynecological cancer or female pelvic anatomy, and involved a truncated discussion among the panel members as compared to the IARC assessment process.

81. The CIR has set forth procedures for its safety assessments (CIR 2018; IMERYS 118788). As discussed in the CIR procedures document, the purpose of the CIR is to *"determine those cosmetic ingredients for which there is a reasonable certainty in the judgement of competent scientists that the ingredient is safe under its conditions of use"*. The same document defines "safety" or "safe" to mean that there is "***no evidence in the available information*** *that*

[43] Dr. Linda Loretz of the PCPC was deposed as a corporate representative of the PCPC on 17 July 2018, 1 October 2018, and 2 October 2018. Mr. Mark Pollack was deposed as a corporate representative of the PCPC on 28 July 2018.

*demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future" [**emphasis** added]*. Based on this definition of *"safe"* and the purpose stated by the CIR, this means that the standard applied to a CIR review, and that should guide the outcome of that review, is whether there is evidence that demonstrates or suggests a hazard. If there is any such evidence of a hazard under conditions of use, then the standard would not be met, and the ingredient should not be deemed safe for use in cosmetics.

82. In the case of talc, a final version of the CIR panel report was published in 2013 (CIR, 2013) and then appeared in the published literature in 2015 (Fiume *et al.* 2015). The CIR panel stated that talc is *"safe in the present practices of use and concentration in cosmetic products"* (CIR, 2013). There was no CIR report published on talc before 2013 even though there was evidence for concern about the safety of talcum powder products that had been voiced within the scientific community for decades and that reliable evidence had been published in peer-reviewed journals even before the CIR came into being in 1978 (as discussed above). Based solely on the CIR standard for safety, existing evidence provided a reasonable basis for finding that the perineal use of talcum powder products increases the risk of ovarian cancer. Moreover, as discussed above with respect to the issue of talc migration, I described how that assessment was incomplete and resulted in conclusions that are not supported by available science.

83. Important evidence in support of my opinions comes from admissions contained in documents and testimony by the trade organization known in the past as the CTFA, and since 2007 known as the PCPC. Publicly available documents show that PCPC has been intimately involved with talc safety issues over the period from the early 1970's up to today (see deposition testimony of Dr. Linda Loretz, page 700). Together with Johnson & Johnson and Imerys, PCPC coordinated and presented a position to regulators and the medical community that talc was safe. This position was presented regardless of significant evidence to the contrary.

84. In their deposition testimony in 2016 and 2018, Mr. Mark Pollak and Dr. Linda Loretz, the designated PCPC corporate representatives, provided details on the close relationship between the CIR panel work generally and the PCPC, as well as the talc review itself. Other

documents available for review confirm the close relationship (*e.g.,* IMERYS 329339 through 329342; IMERYS315001; IMERYS320614; IMERYS281069; IMERYS281536; IMERYS283501; IMERYS322846; IMERYS298968; IMERYS065205; IMERYS118788; PCPC_MDL00103539; PCPC_MDL00009859; PCPC_MDL00009893; PCPC_MDL00009914; PCPC_MDL00009950). This is an important consideration in this case given the role that the CIR plays in cosmetic safety assessments, assessments that are used by manufacturers to assert that their ingredients are safe as required by FDA.

85. Testimony and admissions from PCPC corporate representatives including exhibits to their depositions, are relevant to my opinions because they outline the level of influence on the purportedly independent processes for talc safety assessment by the CIR. To start, the PCPC's president is the chairman of the CIR steering committee that is responsible for choosing the experts that are on the CIR panel, including the talc review in 2013 (deposition of Dr. Loretz pages 842-845; IMERYS118788; trial testimony of Dr. Andersen dated 8/10/2018 pages 3130-3031). The CIR review documents are written not by the expert panel but by CIR staff, who are employees of the PCPC (PCPC0004567; IMERYS118788; trial testimony of Dr. Andersen 8/10/2018). The CIR panel scientists are a standing committee, meaning that the scientists involved do not change that much from review to review, regardless of the issues to be addressed (see deposition of Dr. Linda Loretz pages 842-845; trial testimony of Dr. Andersen 8/10/2018 pages 3132-3133). This is important because the issues related to talc safety are not the typical issues linked to cosmetic ingredients. For most cosmetic ingredients, the issue is not migration internally after perineal application or even use of large amounts of product that can easily suspend in air with each use. Additionally, much of the data that was important in the evaluation of talc as an ingredient in body powders and perineal dusting was human epidemiological data. Yet, the expert panel reviewing talcum powder products and talc as an ingredient in those powders did not include anyone with specific expertise in the unique exposure issues presented or expertise in epidemiology (deposition testimony of Dr. Loretz pages 781, and 838-842). All CIR panel members are paid through the PCPC which in turn is funded by industry, including Johnson & Johnson and Imerys[44]. In fact,

[44] Although Imerys is no longer a member of the PCPC (see deposition testimony of Dr. Loretz), Imerys was a member of the PCPC during the years that talc safety was at issue (1980's, 1990's, 2000's) and during the time of the CIR review of talc (2010-2013). See also IMERYS311275.

records show that many of the CIR panel members made tens of thousands of dollars each year that they served on the CIR panels (see deposition testimony of Dr. Loretz pages 964-974), and that Johnson & Johnson and Imerys were major sources of funding for the PCPC (see deposition testimony of Dr. Loretz pages 829-834) and, consequently, the CIR panel activities. The CIR review of talc was initially started in 2009 but was put on hold for three years before beginning again in 2012 (see trial testimony of Dr. Andersen 8/10/2018 page 3148).

86. Another example of influence on the FDA comes from the industry's response to the filing of two Citizen's Petitions related to adding a cancer warning to talcum powder products. Before continued discussion of the CIR process and industry influences, these events should be examined. This was discussed in the October 1, 2018 Loretz deposition.

87. An important series of events relevant to my opinions occurred with respect to talc related to filing of two Citizen Petitions, one in 1994 and a second in 2008. In 2014, the FDA finally issued a response to those Petitions. In my experience, this is a very long time to wait for an FDA response. As background, the Citizen's Petition process is one that anyone outside of the FDA can use to ask FDA to take, or refrain from taking, an action related to any of the products regulated by FDA (21 CFR Part 10). Two Citizen Petitions were filed by the *Cancer Prevention Coalition,* both related to adding a cancer warning to cosmetic talc products. In the case of the 1994 Petition, Dr. John Bailey, then Acting Director of the Office of Cosmetics and Colors within CFSAN at FDA, responded to the November 1994 Petition on July 11, 1995. Dr. Bailey stated that FDA had not been able to reach a decision on the Petition within the first 180 days of the filing (as required by the regulations) and the reason given was *"because of the limited availability of resources and other agency priorities"* (P-240). In the case of the 1994 and the 2008 Petitions, the FDA did not formally respond to the Petitioner until April 1, 2014 (FDA, 2014). The FDA's 2014 response indicated that FDA was not requiring addition of the specific cancer warning requested by petitioner.

88. Evidence supporting my opinions regarding the influence of industry on FDA's actions is also available. An email dated November 3, 2008 reveals Kathy Wille, Senior Director, Scientific and External Regulatory Policy, Product Stewardship, from Johnson & Johnson *"had a*

side conversation with a key figure from the FDA cosmetic group that is responsible for responding to the Citizen's Petition." The email further states: *"He indicated that the FDA would rule against the petition and would not require warning labels on cosmetic products. But the FDA is looking for* ***scientific support*** *from industry that will help justify their position. She suggested that there is a collective group working to have comments submitted to the FDA."* (IMERYS 250983; IMERYS 281179). *[**emphasis** added]* On July 21, 2009, the PCPC submitted comments on the Petitions to FDA (PCPC_MDL00015494; P-342). A review of the cover letter for the comments reveals that Dr. John Bailey, the same Dr. Bailey that was Acting Director of the Office of Cosmetics and Colors in 1995 and that responded to the first Petition by the Cancer Prevention Coalition, signed the 2009 letter as an employee of the PCPC. The letter was accompanied by a report prepared by Dr. Michael Huncharek and Dr. Joshua Muscat, consultants that had been hired by the PCPC to prepare a response. The defendant's response to the Citizens Petition contained misleading and inaccurate information, including that asbestos had been eliminated from talc which was an issue that was of concern to the FDA (see deposition of Dr. Linda Loretz).

89. Other documents reveal that Dr. Huncharek and Dr. Muscat had been working as consultants for Johnson & Johnson and Imerys for years (JNJ000377405; JNJ000375565; JNJ000391641), providing the companies and/or the PCPC with consulting services related to talc and cancer risk as part of the NTP process in 2000 and 2005 and the IARC process in 2006 (see deposition testimony of Dr. Nicholson dated July 26, 2018 and deposition testimony of Dr. Linda Loretz, Ph.D. October 1, 2018), as well as the talc Citizen Petition response process. Another document shows that in May 2009, PCPC members, including Johnson & Johnson and Imerys, met with FDA to discuss their comments before they were submitted in July 2009 (PCPC0028174-28176; JNJ000092018), even though FDA denied the *Cancer Prevention Coalition* the opportunity for a public hearing to discuss their scientific evidence that the Petitioner had requested both in 1994 and in 2008. The failure of FDA to afford the Petitioner a public hearing and request a more detailed examination of the Petitioner's scientific evidence to elicit a response to questions raised about talc safety in 1994 and in 2008 resulted in a process wherein industry was the sole source of information.

90. The evidence reviewed shows that the FDA did not hold a public hearing which would have allowed for more detailed input from scientists outside of industry. Moreover, as discussed above in some detail, the FDA was not, and has not even today, provided with all available evidence of the existence of the presence of contaminants such as asbestos in cosmetic talcum powder products. As a result, it is my opinion that the conclusions reached by FDA in its 2014 response were not based on an accurate and complete understanding of the composition of talcum powder products. In addition, evidence shows that the FDA was not fully informed about the key role that certain consultants to industry had played in generating some of the scientific studies and review papers that industry has used to support their assertions regarding the safety of talc. For example, the 2003 paper by Huncharek and colleagues (Huncharek *et al.* 2003. *Anticancer Res*. 23:1955-1960) failed to acknowledge that industry had provided support for their work, while later papers failed to acknowledge the full list of industry sponsors of their work (*i.e.*, Huncharek *et al.* 2007. *Eur. J. Cancer Prevent*. 16:422-429; Muscat and Huncharek. 2008. *Eur. J. Cancer Prevent*. 17:139-146; Huncharek and Muscat. 2011. *Eur. J. Cancer Prevent*. 20:501-507; see deposition testimony of Dr. Nicholson dated July 26, 2018). A 2005 response written by Dr. Muscat and Dr. Huncharek to critique the work of Dr. Cramer (Muscat and Huncharek, 2005) also failed to disclose the financial relationship between his work and industry (JNJ000368327; see depositions of Dr. Nicholson and Dr. Loretz).

91. Prior to the CIR review of talc, there were significant events in the 1980's and early 1990's that triggered the need for a safety assessment of the products. The NTP had performed cancer studies in mice and rats in the 1980's that were published in 1993 (NTP, 1993; the report was discussed in detail above). In addition, by 1993, several scientific and/or epidemiological studies had appeared in the scientific literature linking perineal talcum powder product use with ovarian cancer in women (*e.g.*, Henderson *et al.* 1971; Cramer *et al.* 1982; Hartge *et al.* 1983; Whittemore *et al.* 1988; Booth *et al.* 1989; Harlow and Weiss, 1989; Harlow *et al.* 1992; Chen *et al.* 1992; Rosenblatt *et al.* 1992). As a result, a workshop was held in 1994 that was sponsored by industry and the FDA (PCPC_MDL00026142; PCPC_MDL00028481; PCPC_MDL00028665; PCPC0072694; PCPC0075364; P-14). FDA's opening remarks at the workshop indicated that the FDA was wanting input on the *"validity and significance of the existing knowledge regarding the safety of cosmetic talc"* (Carr, 1995). The workshop was run by a group known as the ISRTP, the

International Society for Regulatory Toxicology and Pharmacology. The ISRTP has been described as *"an association dominated by scientists who work for industry trade groups and consulting firms"* (Michaels, 2008). Sponsors of the organization in the past have included major tobacco companies, chemical companies, and drug manufacturing companies (Axelson *et al.* 2003). The ISRTP also publishes a journal (*Regulatory Pharmacology and Toxicology*) and as pointed out by Axelson and colleagues (2003) the articles published often failed to list complete conflicts of interest disclosures. As a result, the ISTRP's activities have been questioned in terms of the level of industry influence that exists (Axelson *et al.* 2003).

92. The ISRTP talc workshop was held in 1994 (January 31 to February 1). The minutes to the meeting are available for review as are the papers that were published after that meeting in the ISRTP journal (1995; volume 21; pages 211-260). One day of the meeting was devoted to the issues related to the NTP cancer studies with talc and the issue of mechanisms of lung carcinogenesis (January 31, 1994), while the second day was devoted to the epidemiological data that had accumulated with respect to talc exposure in women and ovarian cancer and the issue of talc migration (February 1, 1994). Industry-sponsored scientists were among those attending and making comments during the meeting (P-0017). My review of the minutes to the workshop (PCPC0076689-76908; JNJ000008704-8864) as compared to the published summary of the workshop (Carr, 1995) reveals important differences in the actual statements made by scientists at the meeting and the published paper. The paper acknowledges that not all presentations were published. The workshop attendees are listed by Dr. Carr (Carr, 1995) and included 109 participants. At least 67 were from industry or were consultants to industry. Other participants were from government agencies (25 participants) and from academics or public interest groups (17 participants). Key differences in the minutes versus the published summary of the meeting included the fact that not all participants were present at the end of the meeting when the group discussed the workshop findings. Contrary to the statements in the Carr publication regarding *"unanimous assessment"* (Carr, 1995), the statement made on the second afternoon of the workshop was as follows: *"It is not our intent, certainly not mine to strive for consensus, either as a unanimous consensus or a partial consensus which I understand you have to have to use now in describing a consensus…"* (JNJ000008843). Questions were raised by scientists at the meeting on the first day related to the fact that the animal data had limitations but that it still had relevance in

terms of raising questions about the ability of talc to cause lung injury that could lead to cancer. On the second day, one speaker, Dr. Austin, indicated the epidemiological data provided some evidence of an association between talc and ovarian cancer (JNJ000008727). Then, Dr. Brown, another presenter, discussed the issue of talc migration to the ovaries and specifically stated *"the summary of my conclusions is that I believe it can"* (JNJ000008734)). In contrast, the Carr publication states *"Following a presentation by Dr. Brown (university of Wisconsin), the discussion made it clear that available histologic and physiologic studies provide no basis to conclude that talc can migrate to the ovaries from the perineal region"* (page 215 of Carr, 1995). Thus, based on the large amount of information that was not discussed at the ISRTP workshop but was known to industry, it is my opinion that the Carr publication fails to provide an accurate and complete description of the state of the science with respect to talc safety in 1994. Moreover, an important outcome of this workshop was that the signal of talc and human cancer risk existed and could not be ruled out based on discussion at the workshop.

93. Additional evidence which supports my opinions comes from documents describing the industry response to the 1993 NTP publication of findings on talc and cancer in rodents, wherein the NTP concluded that talc was carcinogenic in animals. PCPC along with industry members re-activated the group known as the Talc Interested Party Task Force (*e.g.*, P-14; P-83; P-57). The Talc Interested Party Task Force was first established in the 1970's and reconvened in response to the publication of the paper by Dr. Cramer (Cramer *et al.* 1982), where use of cosmetic talc had been linked with ovarian cancer (P-0845). At this time, the group was led by Johnson & Johnson and the talc ingredient supplier Imerys. Documents from that time show that the goal was to mount a defense strategy around talc and to ensure that the products continued to be sold without regulation (*e.g.*, P-57; P-122; P-86; P-87; P-88; P-90; P-20). Yet, at least in the case of Johnson & Johnson, an outside consultant that had worked with the company for years on talc issues (Dr. Wehner) had suggested in 1994 that studies be performed to answer questions about talc safety, specifically with respect to the risk of ovarian cancer (P-0435). From my review of the depositions and documents, there is evidence that industry had no interest in sponsoring any new research or did not want to spend the money on such research (P-32, see deposition of Dr. Linda Loretz).

94. In formulating my opinions, it was relevant to consider evidence surrounding the activities by industry in the 2000's when NTP was considering whether or not to classify and list talc as a carcinogen as part of its Report on Carcinogens process. As of 1978, Section 301(b)(4) of the Public Health Service Act, as amended, requires that the Secretary of the Department of Health and Human Services (DHHS) publish an annual report on substance use and abuse. The Report on Carcinogens (RoC) is a report that lists all substances that are known to be human carcinogens or may reasonably be anticipated to be human carcinogens. As discussed on the NTP website[45], the first RoC was published in 1980, and since that time, the process has evolved in terms of the way that reviews are performed. In the early RoC process (up through the 7th RoC in 1994), there were formal listing criteria and two categories (*"known human carcinogen"* and *"reasonably anticipated to be a human carcinogen"*) that were determined based on evaluation of cancer studies in humans and/or experimental animals. Starting with the 8th RoC process, the criteria for listing were expanded to include consideration of all relevant information such as mechanistic data. During the period that talc was reviewed as part of the 10th RoC in 2000, the review process included two federal review groups providing initial input on listing recommendations, followed by review by the NTP Board of Scientific Counselors Subcommittee that provided input on listings in a public forum, giving additional opportunities for public and/or industry input. As a result, the first two reviews undertaken were by government scientists and free from outside influence, while the last step in 2000 involved public input and review by a Board that included members from industry (as discussed in more detail below).

95. Deposition testimony and documents show that, in the context of my opinions that industry undertook significant efforts to influence regulatory bodies and the science concerning the safety assessment of talcum powder products, the Center for Regulatory Effectiveness (CRE) played an important role. Based out of Washington, DC, the CRE is a "consulting firm" (http://www.thecre.com/about.html; C&M-LUZ 00013326; IMERYS 226115). The CRE's primary purpose is to provide advice to companies and to intervene on regulatory issues that threaten their business (IMERYS 226115). With respect to talcum powder products, documents show there were two individuals from CRE that were involved: the company's founder and owner, James "Jim" Tozzi and William "Bill" G. Kelly, Jr. Imerys initially retained the CRE in 2000 to

[45] https://ntp.niehs.nih.gov/pubhealth/roc/history/index.html

assist with the 10th RoC process at NTPNTP (IMERYS 100237) and the CRE's consulting work with Imerys continued for more than a decade. Yet, documents show that the CRE represented themselves as being an *"independent"* organization and *"not affiliated"* with any particular industry, company, or other entity. (IMERYS 100151 and MDL_KELLY00014222). Documents also show that CRE efforts on behalf of Imerys led to sufficient confusion regarding the definition of talc such that NTP's Executive Committee reversed the scientists' classification of talc as a carcinogen (IMERYS 330351, IMERYS 303828, IMERYS 110806, IMERYS 209930). CRE efforts on behalf of industry continued with their interaction with the CIR and the production of the 2013 CIR safety assessment of talc (IMERYS 226115; MBS-CRE 000031, MDL_KELLY00017550, MDL_KELLY00014222, MBS-CRE000271).

96. There have been 14 RoC processes to date, the 14th RoC being published in November 2016 (the 15th RoC is in draft form and would be due out this year). Talc was considered as part of the 10th and 12th RoC processes. The 10th RoC meeting where talc was discussed was held in 2000, while the 12th RoC meeting was held in 2005. The 10th RoC deferred action to list talc as a carcinogen, citing a need for additional information; the 12th RoC also deferred action to list talc. It is important to note that the NTP RoC nominated talc for consideration for listing in the 10th RoC based on a review of the available data by a body of scientists without input from industry, and without any direct interaction with other industry groups or representatives with a conflict of interest, consistent with the procedures set forth by IARC for its cancer reviews (IARC, 2006). It is also important to note that a review of the minutes of the 10th RoC indicates that even though the only public comments made to the panel were from industry representatives, many of the reviewers supported listing non-asbestiform talc as reasonably anticipated to be a human carcinogen (IMERYS 039060 through 085). During the 2000 NTP review of talc for listing in the 10th RoC, it is my opinion that Imerys, the PCPC, and Johnson & Johnson made efforts to influence the process and prevent talc from being listed as a carcinogen (*e.g.*, P-0255; P-0012; P-0013; P-0089; P-0317). Documents show that Imerys, with the full knowledge of Johnson & Johnson and PCPC, hired the Center for Regulatory Effectiveness (CRE) in 2000 to submit comments to influence the RoC process without disclosing that defendants coordinated and were directly involved in both the strategy for and the drafting of those comments (IMERYS024243; IMERYS-A_0024244; JNJ 000242897; JNJ 000404803; JNJ 000001699; PCPC0072893; NTP Summary

Minutes, Dec. 13-15, 2000). This effort to influence the process continued into 2001 when the Executive Committee of NTP met and made the decision to defer talc even though the scientists that had reviewed talc had overwhelmingly voted to list talc as a carcinogen (*e.g.*, IMERYS024367; IMERYS 303895-898; P-27; JNJ000013664; JNJ000404511-512; PCPC0066630-672; IMERYS-A_0024411; IMERYS303842; IMERYS288570; IMERYS239852; IMERYS239750; IMERYS239749; IMERYS026529; IMERYS024243; JNJ000008350; JNJ000008344; JNJ000000636; JNJ000368187; JNJ000404425; NTP minutes 2000; IMERYS303828; IMERYS179104; IMERYS208830; IMERYS-A_0024244; PCPC0035777; PCPC0066630). At least by 2002, evidence shows that Imerys was aware of the consequences of listing talc as a carcinogen in terms of product liability issues (P-26; P-3). Evidence shows that industry was aware that, the NTP was more vulnerable to such influence than other bodies such as IARC (P-27). Additional documents provide evidence that efforts to influence the NTP cancer listing process by industry continued in 2004-2005 when talc was scheduled to be considered as part of the 12th RoC process (JNJ00003646-348; IMERYS288692; IMERYS271234; IMERYS035406; JNJ000003436; JNJ000003472; JNJ000375565; JNJ000369203; IMERYS287089; IMERYS324762; IMERYS 236653).

97. IARC has reviewed talc twice, and its conclusions were published first in 1987 and again in 2010. In contrast to the CIR review process which involved a much more cursory review of the science behind over 5000 cosmetic ingredients in the 40 plus years of its existence and only 12 were found to be unsafe for use in cosmetics, IARC was founded in 1965 and in that time has published 122 volumes describing the cancer hazard posed by 1016 different compounds. Of those compounds reviewed by IARC, 120 were found to be *"carcinogenic to humans"*, 82 were found to be *"probably carcinogenic to humans"*, 302 were found to be *"possibly carcinogenic to humans"*, 501 were found to be *"not classifiable as to its carcinogenicity to humans"*, and one compound was found to be *"probably not carcinogenic to humans"*[46]. IARC focuses solely on the issue of cancer hazard and prioritizes its reviews based on compounds where evidence has accumulated indicating there may be a cancer hazard.

[46] https://monographs.iarc.fr/agents-classified-by-the-iarc/

98. In the first assessment of talc (IARC, 1987), the panel met in 1986 and concluded that there was sufficient evidence for human carcinogenicity for talc containing asbestiform fibers (asbestos and fibrous talc) but inadequate evidence for talc not containing asbestiform fibers. Talc with asbestiform fibers was listed as Group 1 (known human carcinogen); talc without asbestiform fibers was listed as Group 3 (not classifiable as to human carcinogenicity). In 2006, IARC again considered the classification of talc as a carcinogen. The working group considered a large body of data available up until 2006, which included a large group of human epidemiological studies examining the risk of ovarian cancer with perineal talc use in women. Although industry was aware that the IARC process was less political (P-27), evidence shows that, consistent with my opinions regarding industry's influence on the talc regulatory processes, industry still initiated efforts to influence the science surrounding talc and cancer risk (JNJ000003914-315; JNJ000004015-4019; JNJ000003969; JNJ000369087; JNJ 000003911; JNJ 000003969). These efforts included having Dr. Muscat, a consultant to industry (IMA-NA0000571; JNJ000369543; Deposition of Joseph Muscat; Muscat000001494; Muscat000001204) attend as an observer and to attempt to influence reviewers with his comments. Other documents provide additional information about the attempts by industry to influence the IARC process in 2006 (*e.g.,* P-0650; P-0204; P-0035; WG-IMA-NA0001554). It is notable that the IARC panel, with less chance of outside influence being asserted, listed talc without asbestiform fibers as a carcinogen (Group 2B; possibly carcinogenic to humans). Following the IARC classification of talc, Imerys elected to add a cancer listing to its MSDS sheet for talc as a possible human carcinogen. Johnson & Johnson has refused to do the same on its MSDS for finished products (JNJ000390337-338; JNJ4T5_000004521-522). The failure of Johnson & Johnson to warn consumers, and even workers that are involved in handling of their products, about the cancer risk associated with use or exposure to talcum powder products is a public health concern. In addition, when talc was listed as a possible human carcinogen by IARC in 2006, documents show that industry continued to promote a message about talc safety by recruiting scientists to publish articles that raised doubt about the link of perineal talc use and ovarian cancer (*e.g.*, P-78; P-92).

99. Returning now to consideration of the CIR process for talc in 2012-2013, documents suggest that industry was intimately involved with the CIR process and its review of talc safety. Important details related to the influence exerted by industry on the overall CIR process

as well as the talc review itself is found in the trial testimony of Dr. Alan Andersen (dated August 11, 2017). Dr. Andersen was in charge of the CIR process and was an employee of the PCPC. Dr. Andersen was responsible for implementation of the talc CIR review process. His testimony and the accompanying documents showed that at least two of the CIR expert panelists that he allowed to participate had conflicts of interest that were not publicly disclosed, and that Mr. Kelly of the CRE provided assistance to the CIR during its talc review. Some of the language in the final CIR talc review documents was copied directly from comments made by the CRE. Additionally, Dr. Andersen was not aware of the fact that the CRE had been hired by Imerys and the talc industry to provide comments to CIR. Additionally, evidence shows that in submitting comments to the CIR, Mr. Kelly of the CRE claimed that *"The Center for Regulatory Effectiveness is not representing a particular company or industry segment in filing these comments [,]"* even though he was working for Imerys at the time (IMERYS 062429). Then, before the review even began, he commented that CRE had established a *"strong relationship with the Cosmetic Ingredient Review."* (IMERYS 226115). Monice Fiume of the CIR staff told Mr. Kelly in 2011, before the review began, *"that CIR would welcome any input from industry on the review at any time."* (IMERYS 065205). Further evidence shows that CIR staff and not the expert panel itself, wrote the talc safety assessment report, and then provided the expert panel with that review as well as comments on the document that had only been made by industry or by consultants to industry (PCPC0004567; IMERYS14817; IMERYS118788; IMERYS065205; IMERYS315001; IMERYS320614; IMERYS281536; IMERYS283501; IMERYS322846; IMERYS298968).

100. It is my opinion as well that information contained in other industry documents, reveal industry efforts to influence scientists and regulators making decisions about talc and its human health risks, were not limited to interactions with the NTP, the FDA and the IARC panel (JNJ000024397; JNJ000379382-384; IMERYS-A_0005090; JNJ000003405; JNJ000381275-276; P-0021; P-0030; P-0031).

VIII. Talc's Human Health Risks and Regulatory Concerns

101. A review of scientific literature and internal company documents from Imerys, Johnson & Johnson, and PCPC shows that the defendants were aware of the human health hazards associated with talc powder products for many decades. Given the presence of asbestos, fibrous

talc, nickel, chromium, and cobalt in the talc body powders manufactured by Imerys and Johnson & Johnson, it is my opinion that a significant human health risk was identified as a hazard related to talcum powder products use at least by the 1940's. These risks included a risk of cancer with exposure to constituents of talcum powder products, and even death with acute inhalation of large amounts of the powder. The following chronology supports my opinions that there is adequate evidence that talcum powder product use is hazard to human health.

- By 1940, the scientific literature contained studies showing that mineral dust exposure, including exposure to talc and asbestos, was associated with lung diseases that could be fatal, and that talc used to manufacture body powders contained both platy talc and fibrous components, including tremolite. Studies by Johnson & Johnson scientists themselves in the 1940's had identified talc as a hazard to human health (Eberl *et al.* 1948).
- By 1950, the scientific literature contained studies showing that talc was associated with adverse tissue reactions in both humans and animals, that the fibrous component of talc was of concern, that exposure to talc in the cosmetic industry itself could produce lung disease, that lung disease due to talc and asbestos was similar, that tremolite dust was an industrial hazard in terms of lung disease, and that even small doses of talc from surgical gloves was linked with adverse tissue reactions, even being described as *"a serious menace in surgery"* (Saxen and Tuovinen, 1947) and as posing a "grave danger" (Eberl *et al.* 1948).
- By 1952, Johnson & Johnson was aware of the adverse tissue reactions linked to talc powders, including the dangers of inhalation of talc (U.S. Patent 2,626,257), even filing a patent for a replacement for talc as a medical dusting powder.
- By 1954, the scientific literature included a report of death in a 10-month old infant due to asphyxiation after aspiration of a large amount of baby powder. It should be noted that reports of such deaths and serious injuries in children continued to occur into the 1960's and 1970's, with one physician suggesting in 1969 the following: *"The widespread ignorance of the dangers of talc aspiration is not surprising, and it is my opinion that these dangers should be better publicized. The direct means of accomplishing this would be a warning statement on each container."* (Moss, M.H. 1969).
- By the mid 1950's, the majority of scientists believed that asbestos could cause lung cancer, and likely other forms of cancer, in humans (Doll, 1955). Evidence for a link of asbestos exposure with lung disease, including lung cancer, was available by the 1930's.

- By the 1950's the scientific literature indicated that asbestos was present in talc, including milled powders (*e.g.,* Dreessen and Dalla Valle, 1935; Millman, N. 1947; Hogue and Mallette, 1949; Schepers and Durkan, 1955). Evidence shows that even today, talcum powder products, including products manufactured and sold by Imerys and Johnson & Johnson included asbestos, fibrous talc, nickel, chromium and cobalt.
- In 1960, the scientific literature included a paper describing the link of ovarian cancer with asbestos exposure (Keal, E.E. 1960). Given that it was known that asbestos was present in talc powder, this paper provided notice that the talcum powder products sold by Johnson & Johnson posed a risk for ovarian cancer as well as lung cancer. Further support for the association of ovarian cancer with exposure to asbestos also was provided in the 1960's (Graham and Graham, 1967).

102. Based on the knowledge available by the 1950's, it is my opinion that talcum powder products manufactured and sold by Imerys and Johnson & Johnson should have warned consumers about the toxic constituents, such as asbestos, fibrous talc, cobalt, nickel, and chromium, in their products and the effects that could be produced by exposure to talc dusts. It is noted that in the 1953 Johnson & Johnson patent, U.S. Patent No. 2,626,257 (filed May 21, 1952), statements warning of adverse human health effects are provided including the following statement: *"Even persons who were not subjected to internal application of talcum have suffered severely from it. Talcum in the respiratory tract is dangerous and has caused severe breathing difficulties to infants, hospital patients and nurses when used carelessly and/or permitted to contaminate the air in large amounts."* Although these statements were made in the patent documents, which may have been seen by lawyers and others involved in intellectual property evaluations, no warnings related to any adverse effect of talcum powder products was made available to the scientific and medical community, regulators, and consumers through statements on packaging of Johnson & Johnson talcum powder products until the 1980's (JNJ000450199-205). Even today, despite the large body of data that has accumulated since the 1950's linking talcum body powder exposure with a risk of cancer, Johnson & Johnson talcum powder products fail to warn consumers about the risks of cancer linked to talc exposure.

103. The issue of safety concerns related to talcum powder products and the failure of companies to warn consumers about serious adverse health effects is of particular importance in the case of a cosmetic product, such as Johnson's Baby Powder, Shower-To-Shower and Shimmer. This is due to the regulatory process in place in the United States related to cosmetics. As discussed above, and unlike the regulation of drugs, devices, and food additives, the responsibility for safety assessment of cosmetic ingredients and products is the responsibility of the cosmetic ingredient and product manufacturers, not the FDA. Cosmetics do not undergo any premarket approval process at FDA. As a result, it is the cosmetic manufacturer, and/or the cosmetic ingredient manufacturer, that is responsible for assuring that the products sold to the consumers, and the ingredients in those products, are safe for use (*Federal Register* 40(42) March 3, 1975). Moreover, there is no benefit assessment made for cosmetic products. In 1966, Johnson & Johnson was aware that their products were considered to have no health benefit (JNJNL61_000039194). This is consistent with the cosmetic regulatory paradigm that is only based on weighing risks of ingredients and products, not benefits.

104. Manufacturers of cosmetic ingredients and finished cosmetic products have a responsibility to continually monitor the scientific information that develops over time to determine if the risks associated with an ingredient, and/or a product, changes due to things such as previously unknown information, development of additional supporting information that may alter the existing safety profile of a product, and even identification of unanticipated safety concerns that can arise with real world use of products. In other words, the responsibility of the manufacturer does not end once an initial safety determination has been made.

105. As already discussed, the regulation is as follows (21 CFR 740.1(a)): *"The label of a cosmetic product* ***shall bear a warning statement*** *whenever necessary or appropriate* ***to prevent a health hazard that may be associated with the product****."* This statement means that the standard that must be met when deciding whether to add a warning to the label of a cosmetic warning is whether there is a possibility of a health hazard and that it could be prevented. In the current case, that "possibility" is of cancer occurring in humans using the body powders for genital dusting. The prevention issue would be related to warning consumers not to use the powders for genital dusting. As discussed in detail above, based on the available scientific data as well as my

education, training, and experience, it is my opinion to a reasonable degree of scientific certainty that Imerys and Johnson & Johnson should have initiated actions to add a warning to the labeling of talcum powder products at least by the 1950's that described the adverse health effects linked to talc body powder exposure. Specifically, a warning about serious tissue toxicity and the increased risk of ovarian cancer with use of talcum powder products should have been included on the product labeling.

106. In order to add warnings to a product, the company must be aware of the risk, which is why I have outlined what was known and when it was known (discussed above in detail). A review of internal company documents, documents from Johnson & Johnson, Imerys, and the PCPC shows that talc ingredient manufacturers and the manufacturers of talcum powder products were following the published literature and were also intimately involved in the safety assessments of talc over the years (*e.g.*, IMERYS 052752 through 754; P-81; see Shripal Sharma deposition dated 9/26/2012; see John Hopkins depositions dated 10/26/2012, 8/16/2018 and 8/17/2018; and see depositions of Dr. Linda Loretz). Thus, the defendants were at least aware for decades that ovarian cancer *may* be associated with the use of talcum powder products.

107. It is important to note that Johnson & Johnson has undertaken efforts to improve the safety of its products used on babies, which would include its talcum powder products. In 2012, Johnson & Johnson made the decision to remove certain harmful chemicals from its baby products including the IARC Group 2B carcinogen triclosan (see *e.g.*, P-38). This action is in conflict with the company's position on talc, also an IARC 2B carcinogen, where Johnson & Johnson did not include a warning to consumers about the risks associated with genital talc use. Then, in 2018, Johnson and Johnson initiated actions to overhaul its baby product line to be more "natural," by removing artificial ingredients and becoming more transparent in terms of the actual ingredients in its products, including Johnson's Baby Powder. These actions have not led to removal of talc, or other constituents of its body powder, from its products and their products still fail to provide a warning to consumers about the cancer risk associated with talcum powder products. Instead, by using the word "natural" the companies are now suggesting an improved safety profile despite no substantive changes in the risks linked with the product.

108. Another action that Johnson & Johnson has taken is developing an alternative line of body powders based on the use of cornstarch instead of talc. Johnson & Johnson investigated an alternative body powder product based on cornstarch instead of talc as early as the 1960's (JNJ000265536-538; see Cornstarch Fact Book JNJTALC000864509). Johnson & Johnson filed a patent in 1952 that issued in 1953 for medical dusting powders that were cornstarch-based powders and in that patent identified the significant toxicity associated with talc powders (U.S. Patent 2,626, 257). The text of the patent describes the toxicity of talc in tissue as a reason for finding a replacement. On February 21, 1964, a Johnson & Johnson Memo regarding cornstarch development states, *"…**it replaced talc because it was found to be absorbed safely in the vagina whereas, of course, talc was not**." [**emphasis** added]* (JNJ000265536-265538) Throughout the 1960's and 1970's, Johnson & Johnson continued to develop cornstarch as a body powder product (*e,g.,* JNJ000265482-483; JNJ000253830-832; JNJ000245901-903; JNJ000245744-748; JNJ000244094-095; JNJ000526750; JNJ000404860; JNJ000279507; JNJ000245762; JNJ000011150; JNJ000026987; JNJ000245678; JNJTALC000866104; JNJ00006987-7007). Important in this process was the fact that the company performed test marketing of a cornstarch Johnson's Baby Powder product in 1977 and found that the cornstarch product *"has been accepted by the consumer as a formula replacement"* (JNJ000245679). In 1978, the FDA's OTC Monograph for skin protectant products (*i.e.,* body powders) listed cornstarch as Generally Recognized as Safe and Effective (GRASE) for use in OTC products (JNJ000470844-846; JNJ000348778) and even noted that cornstarch was recognized as being superior to talc in terms of safety and efficacy (JNJ000470846; JNJ000019415). Therefore, at least by the 1970's, Johnson & Johnson had identified a replacement ingredient for its talcum powder products that they knew was safe and provided the desired cosmetic properties. With respect to the issue of talc as compared to cornstarch powders and ovarian cancer risk, one study has reported that cornstarch is "not predicted to be a risk factor for ovarian cancer" (Whysner and Mohan, 2000). With respect to alternative talcum powder products, Imerys has begun work to produce a synthetic talc powder product (Claverie *et al.* 2018; Imerys 2017-2018 Annual Report); such synthetic talc powder should be able to be produced such that it would be free of constituents such as fibrous talc, asbestos, and heavy metals.

109. With respect to Imerys specifically and this issue of warning consumers about risks linked to products, in another internal document (IMERYS 284935 through 937), the importance of the public safety issues surrounding talc, and women's health in particular, were acknowledged by industry. Documents support my opinion that industry was aware of the need to warn consumers of the cancer risk issue in 2006 (P-0033). Yet, no actions were taken to inform the consumer about the risks associated with talc products. Evidence shows that Imerys began drafting a proposal to FDA wherein industry suggests voluntarily phasing out the production and sale of all cosmetic talc products used for consumer dusting powders that could reasonably be anticipated to be used by women for perineal applications and also to assist the FDA in developing a warning label for body powders containing talc that would warn of the danger of genital dusting (IMERYS 284935 through 937 (P-341)) Importantly, no withdrawal has occurred to date, and there is no warning statement on Johnson & Johnson talcum powder products that refers to the risk of cancer of any type, including ovarian cancer with genital dusting.

110. Johnson & Johnson has never placed a warning on its talcum powder products in order to inform consumers about the serious health risks associated with use of their products. The labeling is, and was, inadequate to inform consumers about the risks associated with use of its products, including the risk of cancer. Given that MSDS sheets are not supplied to consumers of talcum powder products, Imerys also failed to ensure that consumers were warned of the risk of cancer associated with genital talc use (IMERYS328096). Placing a warning on the talcum powder product labels would be an important step towards informing consumers of the hazard associated with repeated use of the products for genital dusting.

111. In a survey of the commercial market over the last year, I identified several talcum body powder products that have included a consumer warning about an increased risk of cancer. Attached in Appendix E to this report is a series of photographs of bottles of body powder that contain such warnings. For example, some of these products state on the labeling: "*Frequent application of talcum powder in the female genital area may increase the risk of ovarian cancer*". This is an example of a warning being placed consistent with 21 CFR 740.1(a).

112. Evidence from other internal corporate documents support my opinions that the defendants were aware that talcum powder products may be associated with a health hazard, which would require a warning on defendants' products. Examples include:

- a 1986 Johnson & Johnson "Technological Forecast" document (P-9) where the company admits that there are continuing health concerns with talc and the safety of cosmetic powders, and that the powders have no health benefit;
- a Johnson & Johnson document dated August 5, 1992 (P-10) discussing declining sales of Baby Powder, including talcum powder products, and the company's desire to grow the powder franchise by targeting minority populations of women (This is a concern given that the same document acknowledges the link of the products with cancer);
- a document from 1997 written by Johnson & Johnson's own toxicology consultant, Dr. Alfred Wehner, where he informed the company about false public statements being made by the PCPC regarding talc safety (P-20); Johnson & Johnson did nothing to correct the false impression left by the PCPC's statements);
- a 1997 document where Johnson & Johnson downplayed the health risks of talc when it responded to media questions about its products (P-115), and failing to acknowledge the role that industry played in the 1994 evaluation by FDA and the fact that reliable scientific evidence had raised a signal for cancer risk;
- a 2000 document from Imerys files where their results from a marketing survey showed the company that "*the general public is not aware of any health issues regarding talc*" (P-24);
- a 2000 internal Imerys email whereby Richard Zazenski agrees with the NTP reviewers that the epidemiology studies are concerning and the data is not dismissible. He may even agree with adding warning labels (IMERYS 240341).
- a 2000 memorandum prepared by Burson-Marsteller for Johnson & Johnson announcing the intent to only use cornstarch beginning December 1, 2000 and discontinuing the use of talc in all consumer products (JNJ000404424 and JNJ000404425);
- a 2001 presentation by Steve Jarvis of Imerys acknowledges that realistically "*there are some health issues with talc*" based on finding for 20 years a "*persistent*

statistical link between the hygienic use of talc and ovarian cancer" (IMERYS 178944);

- a 2008 email from Todd True, former Global Creative Director for Johnson & Johnson says, "*The reality that **talc is unsafe** for use on/around babies is disturbing. I don't mind selling talc, I just don't think we can continue to call it Baby Powder and keep it in the baby aisle.*" Fred Koberna, another Johnson & Johnson employee, responds, "*My understanding is that we introduced the cornstarch variant as an alternative to talc for use on babies. Due to the talc issue and some doctors recommending for moms not use powder on their babies, we don't promote powder to moms.*" Mr. True responded, "*I am on a bit of a mission to strongly consider removing talc from the baby aisle.*" (JNJ000457161) *[**emphasis** added]*
- a 2009 memo by Imerys criticizing Johnson & Johnson for preferring to purchase talc based on cost rather than quality (P-560); and
- two documents related to Johnson & Johnson's pharmacovigilance assessments in 2012 through 2014 (P-882 and P-883) where employees had determined a causal connection between talc body powder use and certain cases of ovarian cancer reported to the company, but the decision was made to remove the language about causality from the records for those cases.

113. Documents in company files also reveal that in November 1994, Johnson & Johnson received a letter from Dr. Samuel Epstein, chairman of the group known as the Cancer Prevention Coalition (P-18), notifying the CEO of Johnson & Johnson of the filing of the Citizens' Petition. In that letter, Dr. Epstein requested that talc products be withdrawn from the market due to the concern with human cancer, or that, at least, a label warning should be required for consumers regarding the concerns of ovarian cancer with talc use. On behalf of industry, PCPC filed comments in 2009. Although industry disagreed with Dr. Epstein's position, it agreed that reasonable scientists looking at the data could disagree with industry, that this disagreement was one that was expressed by responsible scientists over decades, and that defendants could voluntarily change the label without being required to do so by the FDA. Yet, Johnson & Johnson did not warn about the risk of cancer following receipt of their letter. Given the expertise of Dr.

Epstein and the fact that he was pointing to reliable scientific information to support his concerns, Johnson & Johnson had a duty to inform consumers of the potential risks associated with talc use, particularly in women using body powders for genital application.

114. Other industry actions related to talc and the safe use of talc powders in humans that inform my opinions and warrant discussion include the removal of talc powder as a lubricant for condoms and for surgical gloves. With respect to use of talc powder on condoms, manufacturers decided in 1996 to no longer use talc on condoms (IMERYS-A_0011817; January 16, 1996 article in Asbury Park Press; P-0019). The decision was driven in part by the opinions expressed by scientists in the published literature concerning the health hazards associated with talc (Kang et al. 1992; Kasper and Chandler, 1995). Talc industry members such as Johnson & Johnson, Imerys and the PCPC were aware of these actions (PCPC_MDL00062175; PCPC0075758). With respect to use of talc powders on surgical gloves, the risks to human health had been recognized in the 1950's (discussed above). In 2016, FDA acted to formally ban use of powders, including talc, on surgical gloves (*Federal Register* December 16, 2016).

115. Documents show that, instead of providing consumers with warnings and safety information regarding use of talcum powder products, industry performed marketing research (*e.g.*, PCPC0077761-77926; P-24). From the results of the market research, industry knew that consumers were unaware of the safety concerns associated with use of talc-based body powders in the genital area. Importantly, during the process of collecting the consumer data, consumers participating were told that the information on the link of talc use with cancer was "hypothetical", even though industry was aware of a wide variety of scientific data where well-respected scientists had concluded that talc posed a cancer hazard to humans. Evidence shows industry also marketed talcum body powders by targeting populations with a known propensity to use talc body powders in the genital area (P-10; P-0374; P-771).

116. Documents show that Defendants recognized the health hazard of talcum powder products and the potential consequences of failing to inform the scientific and medical community, regulators, and consumers of those hazards (P-26; P-27; P-66). They even developed a document

discussing questioning around the safety issue. The document shows that industry understood that data existed supporting the safety concerns.

IX. Conclusions

117. In conclusion, based on my training and experience in pharmacology, toxicology, pharmacokinetics, human health risk assessment, and the regulation of cosmetic products in the United States, it is my opinion to a reasonable degree of scientific certainty that the weight-of-the-evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women. This conclusion is supported by data that includes, but is not limited to the following: (1) the known toxic effects of talc and the other components of talcum powder products; (2) studies that have identified biologically plausible mechanisms for cancer in humans; (3) the likelihood that talc particles can reach the ovaries; (4) the existence of a dose-response relationship for toxicity including the risk of cancer; and (5) the large human database that includes studies conducted over a period of 40 years showing a consistent signal for ovarian cancer in women exposed to talcum powder products.

118. It is also my opinion to a reasonable degree of scientific certainty that the use of talc in cosmetic products does not meet the CIR standard of safety. Given the presence of asbestos, fibrous talc, cobalt, chromium, and nickel, in the talc body powders manufactured by Imerys and Johnson & Johnson, a significant biologically plausible human health risk was identified as a hazard related to talc body powder use at least by the 1940's. These risks included a risk of cancer with exposure to constituents of talc body powders, and even death with acute inhalation of large amounts of the powder. Based on the knowledge available by the 1950's, talc body powders manufactured and sold by Imerys and Johnson & Johnson should have warned consumers about the toxic constituents, such as asbestos, fibrous talc, nickel, chromium and cobalt and fragrance, in their products and the effects that could be produced by exposure to talc dusts. There was evidence from at least the 1960's of the risk of ovarian cancer in women exposed to components of talc body powders, evidence that only gained strength over the last 30 years. The CIR standard states that there is "no evidence" that demonstrates grounds to suspect a hazard to the public under conditions of use. Based upon my review of the scientific evidence, it is my opinion within a reasonable degree of scientific certainty that talc-based cosmetic products, including products used

by women for genital dusting, should have been labeled to warn of the risk of ovarian cancer with such use. This specific ovarian cancer risk was evident by the 1960's given the presence of asbestos in talc body powders. This opinion is based on the FDA regulations that state that *"the label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product"* (21 CFR 740.1(a)). Cause and effect do not have to be proven for such a warning to be put into place. Given that there has never been an adequate warning placed onto the containers of talcum powder products, the failure to provide consumers with such information puts public health at risk.

119. Finally, it is my opinion to a reasonable degree of scientific certainty that industry worked together with the PCPC to influence the scientific and regulatory processes related to cosmetic talcum powder products such that the scientific and medical communities, as well as consumers, were not provided with important safety information about use of the products.

120. I hereby certify that this report is a complete and accurate statement of all my opinions, and the basis and reasons for them, to which I will testify under oath.

X. Compensation

121. My compensation for litigation work, for both defense attorneys and plaintiff attorneys, is at the rate of $300.00 per hour.

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APPENDIX A

Curriculum Vita

APPENDIX B

Trial List

APPENDIX C

List of Materials and Data Considered

APPENDIX D

Chemicals in the Johnson & Johnson Body Powder Fragrance with Irritant Properties

APPENDIX E

Photographs of Body Powder Products and Their Warnings

APPENDIX A

Curriculum Vitae

CURRICULUM VITAE

Laura M. Plunkett, Ph.D., D.A.B.T

ADDRESS 1127 Eldridge Pkwy, Suite 300-335
Houston, TX 77077

EDUCATION

1984	Ph.D.	Pharmacology	University of Georgia
1980	B.S.	Zoology	University of Georgia

PROFESSIONAL EXPERIENCE

Registered Patent Agent Licata & Tyrrell, P.C., Marlton, N.J., 1999 – present
Assists clients with obtaining patent protection, specializing in products used in medical applications (drugs, devices, dietary supplements). Assists clients with developing regulatory strategies for commercialization of their inventions. Provides regulatory support for companies engaged in manufacturing and marketing of products regulated by the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency and other regulatory bodies in the U.S. and worldwide.

President. Integrative Biostrategies (IB) LLC, 2001- present
Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and Drug Administration. Provides litigation support services as both consulting expert and testifying expert.

Owner. Plunkett & Associates, Houston, Texas, 1997 – 2001
Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and Drug Administration. Provided litigation support services as both consulting expert and testifying expert.

Manager. ENVIRON Corporation, Houston, Texas, 1992 – 1997
Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and

Drug Administration. Provided litigation support services as both consulting expert and testifying expert.

Manager. ENVIRON Corporation, Arlington, Virginia, 1989 – 1992

Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and Drug administration.

Assistant Professor. University of Arkansas for Medical Sciences, Department of Pharmacology and Toxicology, 1986 – 1989

Taught medical and graduate student courses in pharmacology (lecture and laboratory), neurosciences, cardiovascular pharmacology, and neuropharmacology. Performed basic research in area of autonomic control of cardiovascular function and neurochemical systems involved in autonomic function. Recipient of extramural funding from the Arkansas Heart Association (principal investigator).

Postdoctoral fellow. National Institute of General Medical Sciences, Pharmacology Research Associate Training Program, 1984 – 1986

Performed basic research in area of neurochemical control of cardiovascular function and neurochemical systems involved in autonomic function.

Research Assistant. University of Georgia, College of Pharmacy, Department of Pharmacology and Toxicology 1980 – 1984

Taught laboratory courses in pharmacology to pharmacy students as part of graduate student assistantship responsibilities.

HONORS AND AWARDS

Chosen for PRAT program at National Institutes of Health. Pharmacology Research Associate Training Program, 1984-1986.

Rho Chi. The University of Georgia, College of Pharmacy, Initiated, 1984.

Recipient of Excellence in Graduate Research Award. The University of Georgia, College of Pharmacy, 1983.

Alpha Lambda Delta. The University of Georgia Chapter, 1978.

PROFESSIONAL CERTIFICATION

Registered patent agent, 1999 [Registration No. 45,015]

Diplomate, American Board of Toxicology, 1993 to present.

ACADEMIC AFFILIATION

Adjunct Professor. Baylor University, Department of Environmental Science, 2017-present

PROFESSIONAL MEMBERSHIPS

Member, Society of Toxicology 1992 – present

Member, Lone Star Chapter Society of Toxicology 2007 – present

Councilor, Lone Star Chapter Society of Toxicology 2010 - 2013

Secretary, Lone Star Chapter Society of Toxicology 2013 – 2015

Vice President, Lone Star Chapter Society of Toxicology 2015-2016

President, Lone Star Chapter, Society of Toxicology 2016-2017

Past President, Lone Star Chapter, Society of Toxicology 2017-2018

Member, American College of Toxicology, 1997 - present

Member, Society for Risk Analysis, 2007- present

President, Lone Star Chapter of the Society for Risk Analysis, 1998

Councilor, Lone Star Chapter of the Society for Risk Analysis, 1999-2000

Member, Society for Neuroscience 1985 - present

Member, American Association for Pharmaceutical Sciences 1992 - present

Member, ASTM Committee E06, 1990 – present

PUBLICATIONS

1. Rajendran, N, Seagrave, JC, **Plunkett, LM**, MacGregor, JA. A comparative assessment of the acute inhalation toxicity of vanadium compounds. *Inhal. Toxicol.* 2016. 28:618-628.

2. Cox, LA, Popken, DA, Kaplan, AM, **Plunkett, LM**, Becker, RA. How well can in vitro data predict in vivo effects of chemicals? Rodent carcinogenicity as a case study. *Regul. Toxicol. Pharmacol.* 2016. 77:54-64.

3. **Plunkett, LM**, Kaplan, AM, Becker, RA. Challenges in using the ToxRefDB as a resource for toxicity modeling. *Regul. Toxicol Pharmacol*. 2015. 72:610-614.

4. **Plunkett, LM**, Becker, RA, Kaplan, M. An enhanced tiered toxicity testing framework with triggers for assessing hazards and risks of commodity chemicals. *Regul. Toxicol. Pharmacol*. 2010. 58:382-394.

5. Chambers, A, Krewski, D, Birkett, N, **Plunkett, L,** Hertzberg, R, Danzeisen, R, Aggett, PJ, Starr, TB , Baker, S, Dourson, M, Jones, P, Keen, CL , Meek, B, Schoeny, R, and Slob, W *J.* An exposure-response curve for copper excess and deficiency. *Toxicol. Environ. Health.* 2010. 13:546- 578.

6. Krewski, D, Chambers, A, Stern, BA, Aggett, PA, **Plunkett, L,** Rudenko, L. Development of a copper database for exposure-response analysis. *J. Toxicol. Environ. Health.* 2010. 73:208-216.

7. **Plunkett, LM**, Becker, RA. Does the standard toxicological testing paradigm for industrial chemicals apply to screening for children's health risks? *The Open Toxicol. J.* 2008, 2:42-60.

8. Becker, RA, **Plunkett, LM**, Borzelleca, JF, Kaplan, AM. Tiered toxicity testing: Evaluation of toxicity-based decision triggers for human health hazard characterization. *Food Chem. Toxicol*. 2007, 45:2454-2469.

9. MacGregor, JA, **Plunkett, LM**, Youngren, SH, Manley, A, Plunkett, JB, Starr, TB. Humans Appear No More Sensitive than Laboratory Animals to the Inhibition of Red Blood Cell Cholinesterase by Dichlorvos (DDVP). *Regul. Toxicol. Pharmacol*., 2005, 43:150-167.

10. **Plunkett, LM.** Do current FIFRA guideline tests protect infants and children? Lead as a case study. *J Regul Toxicol Pharmacol* 1999;29:80-87.

11. **Plunkett, LM,** Seifen E, Kennedy RH. Effect of morphine pretreatment on cocaine cardiotoxicity in anesthetized guinea pigs. *Arch Int Pharmacodyn* 1989;297:60-67.

12. Zorbas M., Owens SM, **Plunkett LM,** Bui H. The pharmacokinetics of [3H]-[1-(2-thienyl)cyclohexyl]piperidine (TCP) in Sprague Dawley rats. *J Drug Metab Disposit* 1989;17:641-645.

13. Seifen E, **Plunkett LM,** Kennedy RH. Cardiovascular and lethal effects of cocaine in anesthetized dogs and guinea pigs. *Arch Int Pharmacodyn* 1989;300:241-253.

14. McCarty R, **Plunkett LM.** Regulation of binding sites for atrial natriuretic factor (ANF) in rat brain. *Peptides* 1988;9(S1):3-8.

15. Stewart RE, Swithers SE, **Plunkett LM,** McCarty R. ANF receptors: distribution and regulation in central and peripheral tissues. *Neurosci Biobehav Rev* 1988;12:151-168.

16. **Plunkett LM,** Tackett RL. Central dopamine receptors and their role in digoxin-induced cardiotoxicity in the dog. *J Pharm Pharmacol* 1987;39:29-34.

17. **Plunkett LM,** Tackett RL. Increases in CSF norepinephrine associated with the onset of cardiac glycoside toxicity. *Eur J Pharmacol* 1987;136:119-122.

18. McCarty R, **Plunkett LM.** Quantitative autoradiographic analysis of somatostatin binding sites in discrete areas of rat brain. *Brain Res Bull* 1987;18:289-94.

19. **Plunkett LM,** Shigematsu K, Kurihara M, Saavedra JM. Localization of angiotensin II receptors along the anteroventral-third ventricle area of the rat brain. *Brain Res* 1987;405:205-212.

20. Israel A, **Plunkett LM,** Saavedra JM. Increased number of angiotensin II binding sites determined by autoradiography in anterior pituitary of water deprived and Brattleboro rats. *Neuroendocrinol* 1986;42:57-63.

21. Saavedra JM, Correa FMA, **Plunkett LM,** Israel A, Kurihara M, Shigematsu K. Angiotensin and atrial natriuretic peptide binding in brain of hypertensive rats. *Nature* 1986;320:758-760.

22. McCarty RM, **Plunkett LM.** Forebrain atriopeptin binding sites: Alterations in spontaneously hypertensive rats. *Neurochem Int* 1986;9:177-183.

23. Shigematsu K, Saavedra JM, **Plunkett LM,** Kurihara M, Correa FMA. Angiotensin II binding sites in the anteroventral-third-ventricle (AV3V) area and related structures

of the rat brain. *Neurosci Lett* 1986 67:37-41.

24. Correa FMA, **Plunkett LM,** Saavedra JM. Quantitative distribution of angiotensin-converting enzyme (kininase II) in discrete areas of the rat brain by autoradiography with computerized microdensitometry. *Brain Res* 1986;275:259-266.

25. Saavedra JM, Israel A, **Plunkett LM,** Kurihara M, Shigematsu K, Correa FMA. Quantitative distribution of angiotensin II binding sites in rat brain by autoradiography. Peptides 1986;7:679-687.

26. McCarty R, **Plunkett LM**. Binding sites for atrial natriuretic factor (ANF) in brain: alterations in Brattleboro rats. *Brain Res Bull* 1986;17:767-772.

27. **Plunkett LM,** Gokhale RD, Vallner JJ, Tackett RL. Prazosin alters free and total plasma digoxin in dogs. *Am Heart J* 1985;109:847-851.

28. **Plunkett LM,** Tackett RL. The effects of central beta-receptor antagonism on digoxin cardiotoxicity. *Res Comm Chem Path Pharmacol* 1985;48:209-220.

29. Israel A, Saavedra JM, **Plunkett L.** Water deprivation upregulates angiotensin II receptors in rat anterior pituitary. *Am J Physiol* 1985;248 (Endocrino. Metabl. II):E264-E267.

30. Niwa M, Shigematsu K**, Plunkett L,** Saavedra JM. High affinity substance P binding sites in rat sympathetic ganglia. *Am J Physiol* 1985;249 (Heart Circ. Physiol 18):H694-H697.

31. Correa FMA, **Plunkett LM,** Saavedra JM, Hichens M. Quantitative autoradiographic determination of angiotensin-converting enzyme (kininase II) kinetics in individual rat brain nuclei with 125I-351A, a specific enzyme inhibitor. *Brain Res* 1985;347:192-195.

32. Israel A, Niwa M, **Plunkett LM,** Saavedra JM. High affinity angiotensin receptors in rat adrenal medulla. *Regul Pept* 1985;11:237-243.

33. Israel A, **Plunkett LM,** Saavedra JM. Quantitative autoradiographic characterization of receptors for angiotensin II and other neuropeptides in individual brain nuclei and peripheral tissues from single rats. *Cell Mol Neurobiol* 1985;5:211-222.

34. **Plunkett LM,** Correa FMA, Saavedra JM. Quantitative autoradiographic determination of angiotensin-converting enzyme kinetics in rat pituitary and adrenal

glands with 125I-135A, a specific inhibitor. Regul Pept 1985;12:1-10.

35. **Plunkett LM,** Saavedra JM. Increased angiotensin II binding affinity in the nucleus tractus solitarius of spontaneously hypertensive rats. *Proc Natl Acad Sci* 1985;82:7721-7724.

36. **Plunkett LM,** Tackett RL. Central alpha receptors and their role in digoxin cardiotoxicity. *J Pharmacol Exp Ther* 1983;227:683-686.

ABSTRACTS

1. **Plunkett, LM**. Marijuana and Public Safety Concerns: States in Charge. Presenting at Society of Toxicology annual meeting. March 11-15, 2016, San Antonio, Texas.

2. Cox, LA, Popken, DA, Kaplan, AM, **Plunkett, LM**, Becker, RA. How well do High Throughput Screening (HTS) assay data predict in vivo rodent carcinogenicity of pesticides? Presenting at Society for Risk Analysis annual meeting, December 11-15, 2016, San Diego, California.

3. **Plunkett, LM**. THC and legal issues related to the state of the science. Symposium presenter at the Society of Toxicology, New Orleans, LA, March 2016.

4. Goyak, K, Alyea, R, Becker, RA, **Plunkett, LM**, Plunkett, JB. Evaluating the ability of high-throughput screening (HTS) assays to capture the biological activity of industrial chemicals. Poster presentation at the Society of Toxicology, New Orleans, LA, March 2016.

5. MacGregor, JA, Plunkett, JB, **Plunkett, LM.** The occurrence of chemically induced lung tumors in rodents as an outcome in NTP chronic bioassays and the impact on cancer classifications. Presented at the Society of Toxicology, San Diego, CA, March 2015.

6. Urban, JD, Thompson, CM, **Plunkett, LM**, Perry, C, Haws, LC. A state of the science of copper reference dose for soil remediation. Presented at the Society of Toxicology, San Diego, CA, March 2015.

7. **Plunkett, LM**, Kaplan, AM, Becker, RA. Evaluation of a tiered toxicity testing decision trigger for assessing reproductive hazards of commodity chemicals. Submitted for presentation at the Society of Toxicology, Phoenix, AZ, March 2014.

8. **Plunkett, L.M.** Overview of key public and worker health concerns in Texas food production. Presented at the Society of Toxicology, San Antonio, TX, March 2012.

9. **Plunkett, L.M.**, Starr, T.B., MacGregor, J.A., Manley, A. Corn oil as a causative factor for proliferative lesions of the forestaomach in B6C3F1 mice exposed by gavage. Presented at Society of Toxicology, Washington, D.C., March 9, 2011. [Award received for "Best Presentation"]

10. **Plunkett, LM**, MacGregor, JA, Starr, TB, Manley, A. Daily gavage with corn oil is a causative factor for proliferative lesions of the forestaomach in B6C3F1 mice. Toxicology Lett. 189S:S142. Presented at EUROTOX, Dresden, Germany, September 14, 2009.

11. **Plunkett, LM**, MacGregor, JA, Starr, TB, Youngren, SH, Manley, A. Determination of a dichlorvos-specific acute interspecies uncertainty factor. Society of Toxicology, Seattle, WA, March 19, 2008.

12. **Plunkett, LM**, Starr, TB, Youngren, SH, MacGregor, JA, Manley, A. Determination of the magnitude of intraspecies differences in red blood cell cholinesterase inhibition in response to dichlorvos exposure. Society of Toxicology, San Diego, CA, March 6, 2006.

13. **Plunkett, LM**, Licata, JM. What every technology manager needs to know about FDA law. Association of University Technology Managers (AUTM), Orlando, FL, March 4, 2006.

14. **Plunkett, LM,** Licata JM. What every technology manager needs to know about FDA law. Association of University Technology Managers (AUTM), Phoenix, AZ February 2005.

15. **Plunkett, LM**. Qualitative Interpretation of Complex and Disparate Data Sets for Dose-Response Assessment of Essential Trace Elements: Copper as a Case Study. Society for Toxicology, Baltimore, MD March 2004 .

16. **Plunkett, LM.** Evaluating qualitative and quantitative dose-response data in complete data sets for comparative dose-response assessment. Soc. Risk Analysis, Baltimore, MD, December 10, 2003.

17. **Plunkett, LM**, Rieth S, Starr T. Issues in assessing risks for cholinesterase-inhibiting pesticides: A decision tree approach. Soc. Risk Analysis, New Orleans, LA, December 9-12, 1996

18. **Plunkett, LM**, Brown S. Assessment of the potential neuropathic risk to banana workers from dermal exposure to chlorpyrifos. Soc. Risk Analysis, Honolulu, HI, December 3-7, 1995

19. **Plunkett, LM**, Russell K. Cooperation versus Confrontation: Reconciling Lead regulations, exposure studies, and public perception. SEGH Conference, July, Salt Lake City, UT, 1994

20. **Plunkett LM**, Wixtrom RN, Cabrera CR. Evaluation of the long-term safety of inflatable penile prostheses: a critical analysis of potential carcinogenic, reproductive, teratogenic, or adverse immunological effects of silicone. Western Section of American Urological Association Meeting, Seattle, WA, August 21-25, 1994

21. Wixtrom RN, **Plunkett LM**, Clarkin CM. Complications of inflatable penile prostheses: A comprehensive review of infection, mechanical complications, erosion/migration/extrusion, and fibrous capsule formation. 1994.

22. Wixtrom RN, Clarkin CM, Purkait B, **Plunkett LM**. A review of clinical experience with the Mentor Alpha I and Mark II inflatable penile prostheses. 1994.

23. **Plunkett LM**, Rosolowsky LJ, Lerner DM, Washburn ST. A biokinetic model for predicting blood lead levels in adults living near a former battery recycling facility. SEGH Conference, New Orleans, LA, July, 1993.

24. Rosolowsky LJ, Edelmann KG, **Plunkett LM**. A biokinetic model for predicting blood lead levels in adults that accounts for intermittent exposures. Society for Risk Analysis, December, 1993

25. **Plunkett LM**, Owens SM , Gunnell M, Owens RB. The effect of chronic phencyclidine (PCP) and phenylcyclohexene (PC) dosing on [3H]TCP and [3H] haloperidol binding in rat brain. *FASEB J* 1990;4:A329.

26. Owens RB, Owens SM, Gunnell M, **Plunkett LM**. 1990. The effect of chronic phencyclidine (PCP) and phenylcyclohexene (PC) on lymphocyte in subsets in rats. *FASEB J* 1990;4:A337.

27. Zorbas M, Owens SM, **Plunkett LM**, Bui H. [3H]TCP protein binding and pharmacokinetics in Sprague-Dawley rat. *FASEB J* 1989;3:A1036.

28. **Plunkett LM**, Kennedy RH, Seifen E. Effects of chronic stress on myocardial beta-adrenergic receptor binding. *The Pharmacologist* 1988;A1300.

29. Evans, R.E., **Plunkett LM**, Kennedy RH, Seifen E. [3H]Ouabain binding to regions of rat heart as determined by autoradiography. *The Pharmacologist* 1988;A41.

30. Massey BW, **Plunkett LM**, Kennedy RH, Seifen E. Alterations in brain angiotensin II binding in the aged rat. Soc. Neuroscience 1987 Abstracts, p. 722.

31. **Plunkett LM**, Alexander N, Saavedra JM. Altered angiotensin II binding in adrenal gland, pituitary gland and brain of sinoaortic denervated rats. Am. Soc. Hypertension. New York, NY, May 1986.

32. Saavedra JM, **Plunkett LM**, Correa FMA. Increased number of angiotensin II binding sites in the subfornical organ of spontaneously hypertensive rates. Am. Soc. Hypertension, New York, NY, May 1986.

33. **Plunkett LM**, Niwa M, Shigematsu K, Saavedra JM. Increased angiotensin II (ANG) binding in superior cervical ganglia of spontaneously hypertensive rats (SHR). *Fed. Proc* 1985;3: 498.

34. **Plunkett LM**, Saavedra JM. Discrete localization of angiotensin II (ANG) binding sites in rat brainstem by quantitative autoradiography. Neural and Endocrine Peptides and Receptors, Symposium, Washington, D.C., May, 1985.

35. **Plunkett LM**, Israel A, Niwa M, Shigematsu K, Saavedra JM. Alterations in angiotensin II binding in pituitary gland, adrenal gland and superior cervical ganglia of spontaneously hypertensive rats (SHR) as determined by quantitative autoradiography. Neural and Endocrine Peptides and Receptors, Symposium, Washington, DC, May 1985.

36. Shigematsu K, Niwa M, **Plunkett LM**, Saavedra JM. High affinity substance P binding sites in rat sympathetic ganglia. Neural and Endocrine Peptide and Receptors, Symposium '85, Washington, DC, May 1985.

37. McCarty R, **Plunkett LM**, Israel A, Saavedra JM. Quantitation of somatostatin binding sites in rat brain. Neural and Endocrine Peptides and Receptors, Symposium '85, Washington, DC, May, 1985.

38. **Plunkett LM**, Saavedra JM. Increased angiotensin II (ANG) binding in brainstem nuclei of adult spontaneously hypertensive rats (SHR) by quantitative autoradiography. Interamerican Society of Hypertension, Cleveland, OH, May 1985.

39. Saavedra JM, **Plunkett LM**, Niwa M, Israel A, Shigematsu K, R. McCarty, Correa FMA. Autoradiographic-microdensitometric methods for the kinetic analysis of neuropeptide receptors and peptidases in individual brain nuclei. IVth World Congress of Biological Psychiatry, Philadelphia, PA, September, 1985.

40. **Plunkett LM** Saavedra JM. 1985. Altered angiotensin II binding in ganglia and brainstem nuclei of spontaneously hypertensive rats (SHR). Council for High Blood Pressure Research, Cleveland, OH, September 1985.

41. **Plunkett LM**, Correa FMA, Saavedra JM. Quantification of angiotensin-1-converting enzyme kinetics in individual rat pituitary and adrenal glands with 125I-MK351A, a specific enzyme inhibitor. Society for Neuroscience, Dallas, Texas, October 1985.

42. McCarty R**, Plunkett LM**, Shigematsu K, Saavedra JM. Quantitative autoradiographic analysis of somatostatin binding sites in discrete areas of rat brain. Society for Neuroscience, Dallas, Texas, October, 1985.

43. Correa FMA, **Plunkett LM,** Saavedra JM. Quantitative autoradiographic determination of angiotensin-converting enzyme distribution in rat brain with 125I-MK351A, a specific inhibitor. Society for Neuroscience, Dallas, Texas, October 1985.

44. **Plunkett LM,** Saavedra JM. Altered angiotensin II binding kinetics in brainstem, pituitary gland, and adrenal gland in adult SHR. 5th International Symposium on SHR and Related Studies, Tokyo, Japan, October, 1985.

45. **Plunkett LM,** Tackett RL. CSF catecholamine activity decreases during cardiac glycoside-induced arrhythmogenesis. *The Pharmacologist* 1985; 25:745.

46. Tackett RL**, Plunkett LM**. Naloxone inhibits the central hypotensive actions of propranolol. *The Pharmacologist* 1983;25:101.

47. **Plunkett LM,** Vallner JJ, Tackett RL. Prazosin lowers plasma digoxin levels. American Heart Assoc, pp 15, Savannah, GA, 1983.

48. Tackett RL**, Plunkett LM**. 1983. BHT 933 lowers blood pressure and increases cerebrospinal fluid norepinephrine levels. American Heart Assoc, pp 16, Savannah GA, 1983.

49. Bayoumi SM, Gokhale R, **Plunkett L,** Vallner JJ. Pharmacokinetics of clortrimazole in dogs. *Acad. Pharmaceut. Sci* 1983;13(2):204, (Miami meeting).

50. **Plunkett LM,** Tackett RL. Central alpha receptors and their role in digitalis cardiotoxicity. *The Pharmacologist* 1982; 24:489A.

51. **Plunkett LM,** Tackett RL. Central alpha antagonism decreases blood pressure in the dog. Proc. Soc. Exp. Biol. Med. S.E. Sec. 7:12A 1982.

PRESENTATIONS

1. **Plunkett, L.M.** Practical applications of risk assessment. Lecturer at University of Texas Medical Branch at Galveston, Department of Pharmacology and Toxicology. October 19, 2018.

2. **Plunkett, LM.** Non-obviousness and §103. Lecturer at Rutgers School of Law, Camden Campus. November 6, 2012.

3. **Plunkett, LM.** Regulatory primer for pharmacy students: focus on human therapeutics. Invited speaker for the AAPS Visiting Scientist Program, Texas A&M University, College of Pharmacy, Kingsville, TX, May 1, 2009.

4. **Plunkett, LM.** Strategies for reducing adverse drug reactions: Science versus regulatory considerations. Invited speaker for the AAPS Visiting Scientist Program, Texas A&M University, College of Pharmacy, Kingsville, TX, May 1, 2009.

5. **Plunkett, LM.** Novelty requirement of §102. Lecturer at Drexel University School of Law. September 22 and 24, 2008.

6. **Plunkett, LM.** Novelty requirement of §102. Lecturer at Rutgers School of Law, Camden Campus. September 22 and 24, 2008.

7. **Plunkett, LM.** Discussion of the Adequacy of Current Regulatory Risk Assessment Approaches for Protection of Children's Health and the Health of Other "Sensitive" Human Subpopulations. Testimony before the U.S. Senate Enviornment and Public Works Committee. April, 29, 2008.

8. **Plunkett, LM.** Strategies for reducing adverse drug reactions: Science versus regulatory considerations. Invited speaker for the AAPS Visiting Scientist Program, Florida A&M University, Tallahassee, FL, October 26, 2006.

9. **Plunkett, LM**. The guidance as currently implemented: experience with Minnesota's draft risk levels. Presented at the ISRTP workshop entitled: EPA's New (Proposed) Guidance for Assessing Cancer Risks from Early Life Exposures. Genotoxic Mode of Action and Implications for Human Health-Based Standards. Baltimore, MD February 10, 2005.

10. **Plunkett, LM.** An overview of the regulation of products of biotechnology: Who's in charge? Lecturer at University of Houston at Clearlake, November 17, 2004.

11. **Plunkett, LM**. Moderator of the symposium entitled "Regulation of genetically modified cells, foods, organisms and animals for consumer and therapeutic use. Meeting of the American Association of Pharmaceutical Sciences (AAPS), Baltimore, MD, November 11, 2004.

12. **Plunkett, LM**. A Road map to the US Food And Drug Administration Regulations. Invited Speaker and Session Co-chair, Federation of European Biochemical Societies (FEBS), Istanbul, Turkey, October 20-24, 2002.

13. **Plunkett, LM.** An overview of the regulation of products of biotechnology: Who's in charge? Lecturer at University of Houston at Clearlake, November 2001.

14. **Plunkett, LM** . Differences and Similarities Between Children and Adults in their Exposure and Response to Environmental Chemicals: An Update Since 1992. Invited Speaker at ToxForum, Aspen CO, July 2001.

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BOOK CHAPTERS

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2. **Plunkett, LM,** Timmerman, LE. 2011. Pharmacovigilance and Postmarket Surveillance in the United States: The Role of the U.S. Food and Drug Administration. In: Elements of Pharmacovigilance: Be Vigilant, Be Safe. R. Sehgal *et al.* (Eds.), Kongposh Publications: New Dehli.

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5. Saavedra JM, **Plunkett LM**, Correa FMA, Israel A, Kurihara M, Shigematsu K. 1986. Quantitative autoradiography of angiotensin and atrial natriuretic factor binding sites in brain nuclei of spontaneously hypertensive rats. In Brain Peptides and Catecholamines in Cardiovascular Regulation in Normal and Disease States.

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1. **Plunkett LM.** 2008. U.S. Senate Committee on Environment & Public Works. Oral testimony. Full Committee hearing entitled "Oversight on EPA Toxic Chemical Policies". Tuesday, April 29, 2008.

2. **Plunkett LM**, Brett SM. 1991. A new look at lead: sources, exposures, and uptake in populations at risk. ENVIRON Report. 5:6-9.

3. **Plunkett LM**, Frankos VH. 1991. FDA re-examines the safety of silicone gel-filled breast implants. ENVIRON Report. 5:10-13.

APPENDIX B

Trial List

List of Testimony for Dr. Laura M. Plunkett, Ph.D, DABT

Year	Case Name	Law Firm Represented
2013	*Vasquez case* *Court Hearing – 14 November 2013*	Doyle Raizner (Houston, TX)
2013	*Cell Phone Litigation* *Court Hearing – 13 December 2013*	Lundy, Lundy, Soileau & South (Lake Charles, LA)
2013	*Accutane MDL* *Deposition – 16 December 2013*	Matthews & Associates (Houston, TX)
2014	*Ferguson case* *Trial Testimony/Attendance* *26 February – 03 March 2014*	The Law Office of David Mitcham (Houston, TX)
2014	*Shirley case* *Deposition – 09 April 2014*	Ware Jackson (Houston, TX)
2014	*Crum et al v. Burney* *Deposition – 12 May 2014*	The Krueger Law Firm (Mexico, MO)
2014	*Lyles v. MacNeil, Johnson & Johnson, Inc.* *Deposition – 27 May 2014*	Ashcraft & Gerel (Alexandria, VA)
2014	*Mercaptan Litigation (CV-2013-235)* *Deposition – 16 Jun 2014*	J. Patrick Courtney III Law Firm, (Mobile, AL)
2014	*Mercaptan Litigation (CV-2013-235)* *Deposition – 16 Jul 2014*	J. Patrick Courtney III Law Firm, (Mobile, AL)
2014	*Avandia* *Deposition – 19 Aug 2014*	The Rosemond Law Group, (Houston, TX)
2014	*Crum et al v. Burney* *Trial Testimony – 23 October 2014*	The Krueger Law Firm (Mexico, MO)
2014	*Liu case* *Deposition – 11 November 2014*	Farisse Law Firm (Los Angeles, CA)
2015	*Liu case* *Deposition 06 January 2015*	Farisse Law Firm (Los Angeles, CA)

Year	Case Name	Law Firm Represented
2015	*Armstead v. USC, et al.* *Deposition – 06 February 2015*	Dreyer Babich (Los Angeles, CA)
2015	*Broussard v. Multi-Chem Group LLC, et al* *Deposition – 12 March 2015*	Wynne & Wynne (Houston, TX)
2015	*Simoneaux case* *Deposition – 19 March 2015*	Frischhertz, Poulliard, Frischhertz LLC (New Orleans, LA)
2015	*State of Texas v. Calloway* *Trial Testimony – 17 April 2015*	The Silverman Law Group (Austin, TX)
2015	*Wayland Ezeb v. Sandoz Pharmaceuticals, et al* *Deposition – 21 April 2015*	The Javier Law Firm (New Orleans, LA)
2015	*Tylenol – Hayes case* *Deposition – 24 April 2015*	Ashcraft Gerel, LLP (Alexandria, VA)
2015	*Good v. Pfizer, et al.* *Deposition – 10 July 2015*	Law Offices of Todd A. Moore (San Diego, CA)
2015	*Jensen v. Univ. of Washington, et al.* *Deposition – 20 July 2015*	Swanson & Gardner, PLLC (Seattle, WA)
2015	*Good v. Pfiezer, et al* *Deposition – 10 Aug 2015*	Law Offices of Todd A. Moore (San Diego, CA)
2015	*Broussard, et al v. Multi-Chem Group LLC, et al* *Trial Testimony – 14 Sep 2015*	Wynne & Wynne (Houston, TX)
2015	*Paxil* *Deposition – 23 Sep 2015*	Bailey Peavy Bailey (Houston, TX)
2015	*Liu case* *Trial Testimony – 25, 28 Sep 2015*	Farisse Law Firm (Los Angeles, CA)
2015	*Tylenol – Hayes case* *Trial Testimony – 30 Sep 2015*	Ashcraft & Gerel LLP (Alexandria, VA)
2015	*Tobin Horn v. Edward Liscombe, et al* *Deposition – 10 Nov 2015*	Patrick K. Rocchio (New Buffalo, MI)
2015	*Jacoby Moore & Shaquil Byrd v. Janssen, et al.* *Deposition – 01 Dec 2015*	Matthews & Associates (Houston, TX)

Year	Case Name	Law Firm Represented
2016	*VICTORIA KLEIN and ASHLEY SWADLEY, Plaintiffs, VS FEDERAL INSURANCE CO., a/k/a CHUBB GROUP OF INSURANCE COMPANIES; INTERNATIONAL INSURANCE CO., a/k/a WESTCHESTER FIRE INSURANCE CO., n/k/a ACE, USA, Ltd,; Defendants, VS. CVS CAREMARK, as a Successor to CVS REVCO D.S., INC., as a Successor to REVCO D,S.,INC., Third-Party Plaintiff* *Deposition – 13 Jan 2016*	Seeley Savidge Ebert & Gourash (Cleveland OH)
2016	*Brownstein, et al v. Merck, et al* *Deposition – 28 Jan 2016*	Aaron Levine Law Firm (Washington, DC)
2016	*Rader v. GSK (Paxil)* *Deposition – 02 Mar 2016*	Bailey Peavy Bailey (Houston, TX)
2016	*Rader v. GSK (Paxil)* *Expert Testimony – 22 Mar – 23 Mar 2016*	Bailey Peavy Bailey (Houston, TX)
2016	*Tylenol Litigation (Taylor Case)* *Deposition - 19 Apr 2016*	Ashcraft & Gerel, LLP (Alexandria, VA)
2016	*Osteen v. Bayer (Aspirin)* *Deposition -13 May 2016*	Balaban & Spielberger, LLP (Los Angeles, CA)
2016	*Nguyen v. BCBG et al.* *Deposition - 27 May 2016*	Fibich, Leebron, Copeland, Briggs & Josephson (Houston, TX)
2016	*Wayland Ezeb v. Sandoz Pharmaceuticals, et al.* *Trial Testimony – 14Jun -15 Jun 2016*	Javier Law Firm (New Orleans, LA)

Year	Case Name	Law Firm Represented
2016	*Orrick v. GSK (Paxil)* *Deposition - 21 July 2016*	Bailey Peavy Bailey (Houston, TX)
2016	*Freeman v. Roche (Accutane)* *Deposition – 10 Aug 2016*	Krupnick Campbell Malone (Fort Lauderdale, FL)
2016	*Ehrenfelt v. Janssen (Risperdal)* *Deposition – 30 Aug 2016*	Beasley Allen, P.C. (Montgomery, AL)
2016	*Edwards v. Kuy Creek et al* *Deposition – 08 Sep 2016*	Johanson & Fairless, LLP (Sugar Land, TX)
2016	*Tobin Horn v. Edward Liscombe, et al* *Trial Testimony – 09 Nov 2016*	Patrick K. Rocchio (New Buffalo, MI)
2016	*Harper & West v. Janssen (Risperdal)* *Deposition – 11 Nov 2016*	Beasley Allen, P.C. (Montgomery, AL)
2016	*Xarelto MDL* *Deposition – 06 Dec – 07 Dec 2016*	Levin Papatino (Pensacola, FL)
2017	*Talc Litigation* *Deposition – 11 Jan – 13 Jan 2017*	Ashcraft & Gerel LLP (Alexandria, VA)
2017	*Estate of Shirley Reaves v. Dr. Evans* *Deposition – 03 Mar 2017*	Wukela Law Firm (Florence, SC)
2017	*Talc Litigation* *Trial Testimony – 20 Apr – 21 Apr 2017*	Ashcraft & Gerel LLP (Alexandria, VA)
2017	*Stiner v. Amazon, et al.* *Deposition – 09 May 2017*	Brian K. Balser Co., LPA (Elyria, OH)
2017	*Testosterone Gel* *Deposition – 22 May 2017*	Fleming & Associates (Houston, TX)
2017	*Blaes, et al. v. Johnson & Johnson, et al.* *Trial Testimony - 12 Jun – 16 Jun 2017*	Ashcraft & Gerel LLP (Alexandria, VA)
2017	*Echeverria v. Johnson & Johnson* *Sargon Hearing* *26 Jun – 27 Jun 2017*	Ashcraft & Gerel LLP (Alexandria, VA)

Year	Case Name	Law Firm Represented
2017	*Echeverria v. Johnson & Johnson* *Trial Testimony* *27 July, 28 July 2017, 31 July 2017, 1 Aug 2017, 2 Aug 2017*	Ashcraft & Gerel LLP (Alexandria, VA)
2017	*Xarelto Litigation* *Trial testimony* *9 August 2017*	Levin, Papantonio Thomas Mitchell Rafferty & Proctor (Pensacola, FL)
2017	*Couch v. AbbVie* *Trial Testimony* *14 August, 15 August 2017*	Fleming, Nolan & Jez (Houston, TX)
2017	*Tsao v. Ferring* *Deposition* *15 September 2017*	Fleming, Nolan & Jez (Houston, TX)
2017	*Shaquil Byrd v. Janssen* *Trial Testimony* *19 September 2017*	DeGraff, Foy & Kunz, LLP (Albany, NY)
2017	*Edward McDevitt v Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim International GMBH* *Deposition* *05 October 2017*	The Nemeroff Law Firm (Dallas, TX)
2018	*Crochet v. BMS and Otsuka Pharmaceutical* *Deposition* *11 January 2018*	Javier Law Firm (New Orleans, LA)
2018	*Mirena MDL* *Deposition* *19 January 2018*	Jones, Ward (Louisville, KY)
2018	*Synthes case* *Deposition* *24 January 2018*	Nations Law Firm (Atlanta, GA)

Year	Case Name	Law Firm Represented
2018	*Boone v. BIPI* *Trial Testimony* *27-28 February, 01-02 March 2018*	Nemeroff Law Firm (Dallas, TX)
2018	*Gallum v. BIPI* *Trial Testimony* *18-20 April 2018*	Nemeroff Law Firm (Dallas, TX)
2018	*Fluoroquinolones MDL* *Deposition* *25 April 2018*	Baron & Budd, P.C. (Dallas, TX)
2018	*Xarelto MDL* *Cooney case* *Deposition* *24 May 2018*	The Lambert Law Firm (New Orleans, LA)
2018	*Xarelto MDL* *Cooney case* *Trial Testimony* *09 August 2018*	The Lambert Law Firm (New Orleans, LA)
2018	*Pradaxa* *Bedsole v. BIPI* *Trial Testimony* *17th, 18th, 20th, 21st September 2018*	Myers & Flowers (St. Charles, IL)
2018	*McCants v. Vitacost, Inc.* *Deposition* *25 September 2018*	Miller Weisbrod (Dallas, TX)
2018	*Talc* *Brower case Georgia* *Deposition* *28 September 2018*	Beasley Allen (Montgomery, AL)
2018	*Pradaxa* *Knight case (West Virginia)* *Trial Testimony* *04 October – 05 October 2018*	Childers, Schlueter & Smith (Atlanta, GA)

APPENDIX C

List of Materials and Data Considered

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Educational Report and supporting materials of Dr. Thomas Dydek, dated April 9, 2018
Report and supporting materials of Dr. Thomas Dydek, dated August 16, 2018
Report and supporting materials of Dr. Michael Crowley, dated November 12, 2018
Report and supporting materials of Dr. William E. Longo and Dr. Mark Rigler, dated February 28, 2017
Report and supporting materials of Dr. William E. Longo and Dr. Mark Rigler, dated August 2, 2017
Report and supporting materials of Dr. William E. Longo and Dr. Mark Rigler, dated September 2017
Report and supporting materials of Dr. William E. Longo and Dr. Mark Rigler, dated February 16, 2018
Report and supporting materials of Dr. William E. Longo and Dr. Mark Rigler, dated November 14, 2018
Report and supporting materials of Dr. David Madigan, dated January 1, 2018

Trial testimony and exhibits of Susan Nicholson, dated October 24-25, 2016; February 24, 27- 28, 2017; March 1, 2017
Deposition testimony and exhibits of Susan Nicholson, dated July 26-27, 2018
Deposition testimony and exhibits of Patrick Downey, dated August 7-8, 2018
Deposition testimony and exhibits of Tina French, dated August 15, 2018
Deposition testimony and exhibits of Robert Glenn, dated October 18, 2018
Deposition testimony and exhibits Margaret Gurowitz, dated July 12, 2018
Deposition testimony and exhibits of Donald Hicks, dated June 28-29, 2018
Deposition testimony and exhibits of John Hopkins, dated October 19, 2012; August 16-17, 2018; October 17, 2018; November 5, 2018
Trial testimony and exhibits of John Hopkins, February 8, 12-14, 20, 2018
Deposition testimony and exhibits of Linda Loretz, dated July 17, 2018; October 1-2, 2018
Deposition testimony and exhibits of Joseph Muscat, dated September 25, 2018
Deposition testimony and exhibits of Julie Pier, dated September 12-13, 2018
Deposition testimony and exhibits of Mark Pollak, dated August 29, 2018
Deposition testimony and exhibits of Alice Blount, dated April 13, 2018
Deposition testimony and exhibits of Aviam Elkies, dated December 15, 2016
Deposition testimony and exhibits of William Longo, dated August 23, 2017
Trial testimony and exhibits of William Longo, dated May 15-16, 2018; February 20, 2018; June 7, 2018
Deposition testimony and exhibits of David Madigan, dated February 6, 2018; March 13, 2018
Trial testimony and exhibits of Alan Andersen, dated August 10-11, 2018
Deposition testimony and exhibits of Alan Andersen, dated August 18, 2017
Trial testimony and exhibits of Karen Boehler, dated October 26, 2016

Defendant Johnson & Johnson Consumer Inc.'s Supplemental Answer to Plaintiffs' Second Set of Interrogatories. No. 19

Attorneys Eyes Only, Exhibit 1, Exhibit 2 and Exhibit 3

Presentation presented by John M. DeSesso, Ph.D., dated January 18, 2018, Toxic Talc? Anatomy of a Talc Defense

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APPENDIX D

Chemicals in the Johnson & Johnson Body Powder Fragrance with Irritant Properties

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
(d)-Limonene	Y		https://pubchem.ncbi.nlm.nih.gov/compound/440917#section=Safety-and-Hazards *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (96.26%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Health Hazard SYMPTOMS: Symptoms of exposure to this compound may include irritation and sensitization of the skin. It may also cause eye irritation and damage. The substance *is irritating to the skin* and is mildly irritating to the eyes. IPCS, CEC; International Chemical Safety Card on d-Limonene. (April 2005). Available from, as of February 3, 2006: http://www.inchem.org/documents/icsc/icsc/eics0918.htm from HSDB https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+4186 HUMAN EXPOSURE AND TOXICITY: Skin irritation or sensitizing potential was reported following widespread use of this agent in various consumer products. *In humans, oxidation products or metabolites of d-limonene were shown to act as skin irritants. The potential occurrence of skin irritation necessitates regulation of this chemical as an ingredient in cosmetics.* http://www.thegoodscentscompany.com/data/rw1013772.html#tosafty European information : Most important hazard(s): *R 36/38 - Irritating to skin and eyes.* *R 43 - May cause sensitization by skin contact.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317* https://www.ewg.org/guides/substances/151421-dLimonene#.W37iIuhKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive https://cosmeticsinfo.org/ingredient/limonene-0 The safety of Limonene has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Limonene in fragrances because of potential sensitization. In Europe, Limonene is included on the list of "allergenic" substances. The European Cosmetics Directive requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Limonene must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin
1-(2,6,6-Trimethylcyclohex-2-en-1-yl)pent-1-en-3-one	Y		https://pubchem.ncbi.nlm.nih.gov/compound/5375218#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (17.53%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (81.57%): May cause an allergic skin reaction [Warning Sensitization, Skin]*

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			http://www.thegoodscentscompany.com/data/rw1032741.html#tosafty European information : Most important hazard(s): *R 36/37/38 - Irritating to eyes, respiratory system, and skin.*
1,2-Dimethoxy-4-prop-1-en-1-ylbenzene	Y		http://www.thegoodscentscompany.com/data/rw1011132.html#tosafty European information : Most important hazard(s): S 24/25 - Avoid contact with skin and eyes. https://chem.nlm.nih.gov/chemidplus/rn/93-16-3 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/cis-Methylisoeugenol#section=Hazards-Identification Signal: Warning GHS Hazard Statements *H317 (86.67%): May cause an allergic skin reaction [Warning Sensitization, Skin]*
1, 7, 7-Trimethylbicyclol[2.2.1]heptan-2-ol (*Isocamphol, Isobornyl alcohol*)	Y		https://chem.nlm.nih.gov/chemidplus/rn/124-76-5 Skin/eye irritant http://www.thegoodscentscompany.com/data/rw1002092.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* *R 42/43 - May cause sensitization by inhalation and skin contact.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
1-Acetonaphthone	Y		https://pubchem.ncbi.nlm.nih.gov/compound/1_-Acetonaphthone#section=Safety-and-Hazards GHS Hazard Statements *H315 (11.59%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (80.69%): May cause an allergic skin reaction [Warning Sensitization, Skin]*
1-Benzazole (*Indole*)	Y	Y	https://pubchem.ncbi.nlm.nih.gov/compound/798#section=Safety-and-Hazards GHS Hazard Statements *H311 (98.88%): Toxic in contact with skin [Danger Acute toxicity, dermal]* https://chem.nlm.nih.gov/chemidplus/rn/120-72-9 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1006511.html#tosafty European information : Most important hazard(s):

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			R 21/22 - Harmful in contact with skin and if swallowed. *R 37/38 - Irritating to respiratory system and skin.* *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
1-Cedr-8-en-9-yl ethenone (*Methyl cedryl ketone, vertofix*)	Y	Y	https://pubchem.ncbi.nlm.nih.gov/compound/107065#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H317 (94.26%): May cause an allergic skin reaction [Warning Sensitization, Skin]* http://www.thegoodscentscompany.com/data/rw1026472.html#tosafty European information : Most important hazard(s): Xi - Irritant *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.*
1-Methoxy-4-methylbenzene (*p-methylanisole*)		Y	https://pubchem.ncbi.nlm.nih.gov/compound/7731#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (99.65%): Causes skin irritation [Warning Skin corrosion/irritation]* https://chem.nlm.nih.gov/chemidplus/rn/104-93-8 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1003932.html#tosafty European information : Most important hazard(s): *R 38 - Irritating to skin.* S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
1-Methyl-1-(4-methylcyclohex-3-en-1-yl)ethyl acetate (*alpha-Terpinyl acetate*)	Y		http://www.thegoodscentscompany.com/data/rw1011272.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* GHS Label elements, including precautionary statements Signal word Warning Hazard statement(s)

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			H315 - Causes skin irritation
2,6-Dimethylheptan-2-ol (*2,6-Dimethyl-2-heptano Freesia heptanol Dimetol (Givaudan)l*)		Y	https://pubchem.ncbi.nlm.nih.gov/compound/83268#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* https://chem.nlm.nih.gov/chemidplus/rn/13254-34-7 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1024471.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
2-Isopropenyl-5-methylcyclohexanol (*Isopulegol*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/24585#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (82.31%): Causes skin irritation [Warning Skin corrosion/irritation]* http://www.thegoodscentscompany.com/data/rw1449811.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
2-Isopropyl-5-methylcyclohexanol (*Menthol, Menthol, (1 alpha, 2 beta, 5 alpha)-Isomer*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/1254#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (97.9%): Causes skin irritation [Warning Skin corrosion/irritation]* Health Hazard SYMPTOMS: Symptoms of exposure to this compound may include irritation of the skin, eyes, mucous membranes and upper respiratory tract. from CAMEO Chemicals https://chem.nlm.nih.gov/chemidplus/rn/89-78-1 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1029672.html#tosafty European information : Most important hazard(s): Xi - Irritant *R 37/38 - Irritating to respiratory system and skin.* R 41 - Risk of serious damage to eyes. S 24/25 - Avoid contact with skin and eyes.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
2-Nonanone,3-(hydroxymethyl) (*2-Acetyl-1-octanol* *Herbal ketone* *Methyl lavender ketone* - (IFF))		Y	https://pubchem.ncbi.nlm.nih.gov/compound/106823#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]*
2-Octanol,2,6-dimethyl (*2,6-Dimethyloctan-2-ol*)		Y	https://pubchem.ncbi.nlm.nih.gov/compound/86751#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* http://www.thegoodscentscompany.com/data/rw1030292.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
2-Phenylethyl 3-methylbutanoate (*Phenethyl Isovalerate*)	Y		http://www.thegoodscentscompany.com/data/rw1010091.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
2-Phenylethyl formate (*Phenethyl formate* *formic acid, 2-phenylethyl ester*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7711#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements H317 (100%): May cause an allergic skin reaction [Warning Sensitization, Skin] http://www.thegoodscentscompany.com/data/rw1026431.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. S 24/25 - Avoid contact with skin and eyes.
2-Phenylethyl phenylacetate (*Phenethyl phenylacetate*)	Y		http://www.thegoodscentscompany.com/data/rw1010111.html#tosafty European information : Most important hazard(s): *Xi N - Irritant, Dangerous for the environment.* *R 36/38 - Irritating to skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*

<table>
<tr><th colspan="4">Ingredient List – Johnson's Baby Powder & Shower-to-Shower</th></tr>
<tr><th>Chemical</th><th>Baby Powder</th><th>Shower-to-Shower</th><th></th></tr>
<tr><td>2-Propanol, 1,1 '-oxybis-</td><td>Y</td><td>Y</td><td>https://chem.nlm.nih.gov/chemidplus/rn/110-98-5
Skin/eye irritant

https://pubchem.ncbi.nlm.nih.gov/compound/8087#section=Safety-and-Hazards
Signal: Warning
GHS Hazard Statements

H315 (97.83%): Causes skin irritation [Warning Skin corrosion/irritation]

Skin, Eye, and Respiratory Irritations
A skin and eye irritant.
Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2805
from HSDB

Skin Symptoms
Redness.
from ILO-ICSC

NIOSH Toxicity Data
<table>
<tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr>
<tr><td>Skin and Eye Irritation</td><td></td><td>eye /rabbit</td><td>500 mg</td><td>mild</td><td>October 2010</td></tr>
<tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>500 µL/24H</td><td>moderate</td><td>October 2010</td></tr>
</table>
</td></tr>
<tr><td>2-t-Butylcyclohexyl Acetate (2-Tert-Butylcyclohexyl acetate

Green acetate

Verdox (IFF))</td><td></td><td>Y</td><td>http://www.thegoodscentscompany.com/data/rw1002462.html#tosafty
Most important hazard(s):

S 24/25 - Avoid contact with skin and eyes.

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Skin irritation (Category 2), H315</td></tr>
<tr><td>3-(5,5,6-Trimethylbicyclol[2,2.1]hept-2-yl)cyclohexanol

(3-(5,5,6-Trimethyl-2-norbornyl)cyclohexanol

Sandal hexanol

Sandiff (IFF))</td><td>Y</td><td></td><td>https://pubchem.ncbi.nlm.nih.gov/compound/103005#section=Safety-and-Hazards
Signal: Warning
GHS Hazard Statements

H315 (95.2%): Causes skin irritation [Warning Skin corrosion/irritation]

http://www.thegoodscentscompany.com/data/rw1006491.html#tosafty
European information :
Most important hazard(s):
S 24/25 - Avoid contact with skin and eyes.</td></tr>
<tr><td>3, 7-Dimethyloct-6-en-l-ol

(Citronellol)</td><td>Y</td><td>Y</td><td>https://pubchem.ncbi.nlm.nih.gov/compound/8842#section=Safety-and-Hazards
Signal: Warning
GHS Hazard Statements</td></tr>
</table>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			H315 (95.35%): Causes skin irritation [Warning Skin corrosion/irritation] H317 (99.55%): May cause an allergic skin reaction [Warning Sensitization, Skin] Skin, Eye, and Respiratory Irritations */Skin/ moderately irritating.* Opdyke, D.L.J. (ed.). Monographs on Fragrance Raw Materials. New York: Pergamon Press, 1979., p. 235 from HSDB Toxicity Summary HUMAN EXPOSURE AND TOXICITY: Adult male volunteers with no known allergic reactions were patch-tested on their back for 48 hr with 32% citronellol. After 48 hr, patches were removed and the skin was cleaned of any residual test material. Moderate irritation was observed. A patch test using a 1% concentration of citronellol in acetone gave a positive reaction in subjects allergic to citronella oil. ANIMAL STUDIES: Citronellol applied full strength to intact or abraded rabbit skin for 24 hr under occlusion was moderately irritating. Severe irritation was observed in rabbits and guinea pigs exposed to 100% compound (unoccluded) for 24, 48 or 72 hr. from HSDB https://chem.nlm.nih.gov/chemidplus/rn/106-22-9 *Skin/eye irritant* https://www.ewg.org/guides/substances/1285-CITRONELLOL#.W38ssuhKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive https://cosmeticsinfo.org/ingredient/citronellol-0 The safety of Citronellol has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Citronellol in fragrances because of potential sensitization. http://www.thegoodscentscompany.com/data/rw1007032.html#tosafty European information : Most important hazard(s): *R 36/38 - Irritating to skin and eyes.* *R 43 - May cause sensitisation by skin contact.* S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317*
3, 7-Dimethylocta-2,6-dien-1-yl acetate	Y		Neryl Acetate

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
(*Neryl Acetate* *Nerol Acetate*)			https://pubchem.ncbi.nlm.nih.gov/compound/1549025#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (15.29%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (15.29%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Skin, Eye, and Respiratory Irritations In human patch test, geraniol @ 32% concn was severely irritating & geranyl acetate mildly irritating. Motoyoski et al; Cosmet Toiletries 94(8): 41 (1979) from HSDB http://www.thegoodscentscompany.com/data/rw1033552.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.*
3,7-Dimethylocta-2,6-dien-1-yl benzoate (*Trans-3,7-Dimethylocta-2,6-dien-1-yl benzoate, Geranyl Benzoate*)	Y		Trans-3,7-Dimethylocta-2,6-dien-1-yl benzoate or Geranyl Benzoate ???? https://pubchem.ncbi.nlm.nih.gov/compound/5353011#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* http://www.thegoodscentscompany.com/data/rw1024871.html#tosafty European information : Most important hazard(s): S 24/25 - Avoid contact with skin and eyes.
3-Methyl-1H-indole (*Skatole*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/6736#section=GHS-Classification Signal: Warning GHS Hazard Statements with hazard statement code(s): *H315 (96.3%): Causes skin irritation [Warning Skin corrosion/irritation]* http://www.thegoodscentscompany.com/data/rw1006331.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* S 20/21 - When using do not eat, drink or smoke. S 24/25 - Avoid contact with skin and eyes.
3-Methyl-5-(2,2,3-trimethylcyclopent-3-en-1-yl)pentan-2-ol (*Sandal pentanol, Sandalore*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/103212#section=Safety-and-Hazards Signal: Warning http://www.thegoodscentscompany.com/data/rw1026291.html#tosafty European information : Most important hazard(s):

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			Xi - Irritant *R 36/37/38 - Irritating to eyes, respiratory system, and skin.*
3-Methylbutyl salicylate (*Isoamyl Salicylate*)		Y	http://www.thegoodscentscompany.com/data/rw1006772.html#tosafty
3-Phenylpropan-1-ol	Y		https://pubchem.ncbi.nlm.nih.gov/compound/31234#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (98.51%): Causes skin irritation [Warning Skin corrosion/irritation]* Toxicity Summary HUMAN EXPOSURE AND TOXICITY: In a multicenter study, 218 fragrance sensitive patients with proven contact dermatitis were patch tested. Reactions (0.9%) in fragrance sensitive patients were observed with 3-phenylpropanol at 5% in petrolatum. ANIMAL STUDIES: In an irritation study in rabbits 3-phenylpropanol was applied for 24 hr under occlusion at dose levels of 2.5 and 5 g/kg. At 2.5 g/kg, moderate erythema and slight to moderate edema were observed. At 5 g/kg, moderate to severe erythema and moderate edema were observed. In another study in rabbits, 3-phenyl-1-propanol was applied for 24 hr under occlusion at 5 g/kg. Moderate to severe erythema, severe edema, scaling and necrosis were observed. A 0.5 mL aliquot of 3-phenylpropanol was applied to intact and abraded skin for 24 hr under occlusion. Moderate irritation was observed. Necrosis was also observed. from HSDB https://chem.nlm.nih.gov/chemidplus/rn/122-97-4 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1010172.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
4-(2,6,6-Trimethylcyclohex-2-en-1-yl)but-3-en-2-one (*alpha-ionone*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/5282108#section=Safety-and-Hazards Signal: Danger GHS Hazard Statements Skin, Eye, and Respiratory Irritations *alpha-Ionone was found to be a moderate /skin/ irritant.* Lalko J et al; Food Chem Toxicol 45 Suppl 1: S235-40 (2007) from HSDB Toxicity Summary *HUMAN EXPOSURE AND TOXICITY: AI (32 % in acetone) was found to be a moderate irritant*. No reactions were observed with 1% AI; 5% AI produced one irritant/questionable reaction. ANIMAL STUDIES: No skin irritation was observed in miniature swine using neat AI. In guinea pigs AI was reported to be *moderately irritating in skin test*. AI produced *severe skin irritation reaction in rabbits*. AI was tested in a 90-days oral toxicity study using male and female rats.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			from HSDB http://www.thegoodscentscompany.com/data/rw1011952.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *R 42/43 - May cause sensitization by inhalation and skin contact.* S 24/25 - Avoid contact with skin and eyes.
4,7-Methano-IH-indenol, 3a,4,5,6, 7, 7a-hexahydro-, propanoate (*Tricyclodecenyl Propionate*)		Y	https://pubchem.ncbi.nlm.nih.gov/compound/86579#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements https://chem.nlm.nih.gov/chemidplus/rn/17511-60-3 *Skin/eye irritant* https://www.ewg.org/guides/substances/6105-TRICYCLODECENYLPROPIONATE#.W4QRzuhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance lacks data on contact allergy in humans. lOpinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/rw1011151.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
4-Methyl phenyl 2-methylpropanoate (*p-Tolyl isobutyrate* *P-Cresyl isobutyrate*)	Y		http://www.thegoodscentscompany.com/data/rw1035021.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/37/38 - Irritating to eyes, respiratory system, and skin.
5-Isopropenyl-2-methylcyclohex-2-en-1-one (*Carvone*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7439#section=Hazards-Identification Signal: Danger GHS Hazard Statements *H315 (99.37%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (92.11%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Toxicity Summary HUMAN EXPOSURE AND TOXICITY: The sensitizing potential of l-carvone has been considered low, but it has occasionally caused contact allergy in users of spearmint toothpaste and chewing gum. ANIMAL STUDIES: Clinical signs after acute exposure in mice and rats were different depending on the route of exposure.. After acute dermal exposure no systemic or skin effects were observed from HSDB
8-Cyclohexadecen-1-one	Y		https://pubchem.ncbi.nlm.nih.gov/compound/534634#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (68.75%): Causes skin irritation [Warning Skin corrosion/irritation]*

<table>
<tr><th colspan="4">Ingredient List – Johnson's Baby Powder & Shower-to-Shower</th></tr>
<tr><th>Chemical</th><th>Baby Powder</th><th>Shower-to-Shower</th><th></th></tr>
<tr><td>Acetic acid, p-tert-butylcyclohexyl

(4-Tert-butylcyclohexyl acetate)</td><td></td><td>Y</td><td>https://chem.nlm.nih.gov/chemidplus/rn/32210-23-4
Skin/eye irritant

http://www.thegoodscentscompany.com/data/rw1001372.html#tosafty

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Skin irritation (Category 2), H315</td></tr>
<tr><td>Acetic acid, phenylmethyl ester

(Benzyl acetate)</td><td>Y</td><td></td><td>https://pubchem.ncbi.nlm.nih.gov/compound/8785#section=Hazards-Identification
Signal: Danger
GHS Hazard Statements

H315: Causes skin irritation [Warning Skin corrosion/irritation]

Health Hazard
Harmful if inhaled. May be harmful if swallowed or absorbed through the skin. Vapor or mist is irritating to the eyes, mucous membrane and upper respiratory tract. (USCG, 1999)
from CAMEO Chemicals

Skin, Eye, and Respiratory Irritations
... Irritating to skin, eyes, respiratory tract.
Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989., p. 176
from HSDB

NIOSH Toxicity Data
<table><tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>100 mg/24H</td><td>moderate</td><td>October 2017</td></tr></table>
Skin Symptoms
Dry skin.
from ILO-ICSC

https://chem.nlm.nih.gov/chemidplus/rn/140-11-4
Skin/eye irritant

https://www.ewg.org/guides/substances/640-BENZYLACETATE#.W4QdrehKiUk
The European Commission's Scientific Committee on Consumer Safety reports this substance shows negative results for causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive

http://www.thegoodscentscompany.com/data/rw1001612.html#tosafty
European information :
Most important hazard(s):
Xi - Irritant
R 36/37/38 - Irritating to eyes, respiratory system, and skin.</td></tr>
</table>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Aldehyde C-7 (*Heptanal*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/8130#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (99.71%): Causes skin irritation [Warning Skin corrosion/irritation]* https://chem.nlm.nih.gov/chemidplus/rn/111-71-7 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1014291.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/37/38 - Irritating to eyes, respiratory system, and skin. R 50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Alpha-Isomethyl Ionone	Y		https://pubchem.ncbi.nlm.nih.gov/compound/5372174#section=Hazards-Identification Signal: Warning GHS Hazard Statements H315 (80.27%): Causes skin irritation [Warning Skin corrosion/irritation] H317 (90.98%): May cause an allergic skin reaction [Warning Sensitization, Skin] http://www.thegoodscentscompany.com/data/rw1594731.html#tosafty (50% minimum alpha-isomethyl ionone) European information : Most important hazard(s): *Xi N - Irritant, Dangerous for the environment.* *R 38 - Irritating to skin.* *R 43 - May cause sensitisation by skin contact.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin sensitisation (Category 1), H317* (70% minimum alpha-isomethyl ionone) European information : Most important hazard(s): *Xi - Irritant* *R 38 - Irritating to skin.* 02 - Keep out of the reach of children. S 24/25 - Avoid contact with skin and eyes. (80% minimum alpha-isomethyl ionone) European information : Most important hazard(s): *Xi - Irritant* *R 38 - Irritating to skin.* S 24/25 - Avoid contact with skin and eyes.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			(90% minimum alpha-isomethyl ionone) European information : Most important hazard(s): *Xi - Irritant* *R 38 - Irritating to skin.* S 24/25 - Avoid contact with skin and eyes. https://cosmeticsinfo.org/ingredient/alpha-isomethyl-ionone-0 The safety of Alpha-Isomethyl Ionone has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of mixed isomers of methyl ionone (including Alpha-Isomethyl Ionone) in fragrances because of potential sensitization. The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Alpha-Isomethyl Ionone and determined that it was Generally Recognized as Safe (GRAS) for use as a flavoring substance. In Europe, Alpha-Isomethyl Ionone is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Alpha-Isomethyl Ionone must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 https://www.ewg.org/skindeep/ingredient/700295/ALPHA-ISOMETHYL_IONONE/#.W4QmbOhKiUl Allergies/immunotoxicity Possible human immune system toxicant or allergen SCCPNFP (Scientific Committee On Cosmetic Products And Non-Food Products). 1999. Opinion Concerning Fragrance Allergy In Consumers. . SCCNFP/0017/98 Final, December 1999; and SCCPNFP (Scientific Committee On Cosmetic Products And Non-Food Products). 2000. An Initial List Of Perfumery Materials Which Must Not Form Part Of Fragrances Compounds Used In Cosmetic Products. SCCNFP/0320/00, final May 2000.
Amyl Cinnamal (*alpha-Amyl cinnamaldehyde* *alpha-pentylcinnamaldehyde*)	Y	Y	https://chem.nlm.nih.gov/chemidplus/rn/122-40-7 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/1623625#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements H317 (98.8%): May cause an allergic skin reaction [Warning Sensitization, Skin] Skin, Eye, and Respiratory Irritations *A severe skin irritant.* Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 251 from HSDB

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			https://www.ewg.org/guides/substances/368-AMYLCINNAMALDEHYDE#.W4QozuhKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive EPA's review of industry submitted toxicity data and the potential for human exposure concludes that this substance poses a moderate risk for human health. EPA Hazard-Based Prioritizations - Risks - Environmental Protection Agency (EPA) https://cosmeticsinfo.org/ingredient/amyl-cinnamal-0 The safety of Amyl Cinnamal has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Amyl Cinnamal in fragrances because of potential sensitization. More safety Information: Link to FDA Code of Federal Regulations for alpha-amyl cinnamic aldehyde (Amyl Cinnamal): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=cinnamaldehyde The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Amyl Cinnamal does not present a safety concern at current levels of intake when used as a flavoring agent. Link to the JECFA safety evaluation of Amyl Cinnamal: http://www.inchem.org/documents/jecfa/jeceval/jec_123.htm The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Amyl Cinnamal and determined that it was Generally Recognized as Safe for use as a flavoring substance. In Europe, Amyl Cinnamal is included on the list of "allergenic" substances. The European Cosmetics Directive requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Amyl Cinnamal must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1001011.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* R 43 - May cause sensitisation by skin contact. Hazards identification GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Skin sensitisation (Category 1), H317
Anisaldehyde	Y		https://chem.nlm.nih.gov/chemidplus/rn/123-11-5

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
(*P-Anisaldehyde*)			*Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1001272.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. Hazards identification GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Acute toxicity, dermal (Category 5), H313* *Skin corrosion/irritation (Category 3), H316*
Benzaldehyde	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr348.pdf https://chem.nlm.nih.gov/chemidplus/rn/100-52-7 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/240#section=GHS-Classification Signal: Warning GHS Hazard Statements *H312 (52%): Harmful in contact with skin [Warning Acute toxicity, dermal]* *H315 (48%): Causes skin irritation [Warning Skin corrosion/irritation]* Health Hazard Inhalation of concentrated vapor may irritate eyes, nose and throat. Liquid is irritating to the eyes*. Prolonged contact with the skin may cause irritation. (USCG, 1999)* from CAMEO Chemicals Skin, Eye, and Respiratory Irritations *A skin irritant.* Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 353 from HSDB NIOSH Toxicity Data

Measurement	System	Route/Organism	Dose	Effect	Date
Skin and Eye Irritation		skin /rabbit	500 mg/24H	moderate	April 2017

Health Effects
Irritation-Eyes, Nose, Throat, Skin---Moderate (HE15)
from OSHA Chemical Sampling Information

Symptoms
Irritation of eyes, skin, nose, throat; contact dermatitis; INGES. ACUTE: sore throat

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			from OSHA Chemical Sampling Information Skin Symptoms Redness. from ILO-ICSC Toxicity Summary HUMAN EXPOSURE AND TOXICITY: It may cause contact dermatitis.. ANIMAL STUDIES: from HSDB https://www.ewg.org/guides/substances/7337-BENZALDEHYDE#.W4QxU-hKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive https://cosmeticsinfo.org/ingredient/benzaldehyde-0 FDA: Link to the Code of Federal Regulations for Benzaldehyde https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=benzaldehyde Benzaldehyde may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 The Joint FAO/WHO Expert Committee on Food Additives has established an Acceptable Daily Intake of 0-5 mg Benzaldehyde/kg body weight. No safety concern was indicated at current levels of intake when used as a flavoring agent. http://www.inchem.org/documents/jecfa/jeceval/jec_176.htm http://www.thegoodscentscompany.com/data/rw1001491.html#tosafty European information : Most important hazard(s): Xn - Harmful. S 24 - Avoid contact with skin. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317*
Benzaldehyde, 2-hydroxy- (*Salicylaldehyde*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/6998#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H312 (49.04%): Harmful in contact with skin [Warning Acute toxicity, dermal]* *H315 (53.07%): Causes skin irritation [Warning Skin corrosion/irritation]* Health Hazard LIQUID: Irritating to skin and eyes. Harmful if swallowed. (USCG, 1999) from CAMEO Chemicals

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			https://chem.nlm.nih.gov/chemidplus/rn/90-02-8 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1028641.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 21/22 - Harmful in contact with skin and if swallowed.* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
Benzene, 1,3-dimethoxy- (*meta-dimethyl hydroquinone* *m-dimethoxybenzene*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/9025#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H312 (50%): Harmful in contact with skin [Warning Acute toxicity, dermal]* *H315 (50%): Causes skin irritation [Warning Skin corrosion/irritation]* http://www.thegoodscentscompany.com/data/rw1027111.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
Benzene, ethenyl- (*Styrene, vinylbenzene*)	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR673.pdf https://chem.nlm.nih.gov/chemidplus/rn/100-42-5 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/styrene#section=Safety-and-Hazards Signal: Danger GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* Health Hazard *Moderate irritation of eyes and skin*. High vapor concentrations cause dizziness, drunkeness, and anesthesia. (USCG, 1999) from CAMEO Chemicals Skin, Eye, and Respiratory Irritations *Irritating to skin* ... Commission of the European Communities. Legislation on Dangerous Substances - Classification and Labelling in the European Communities. Vol. II. London and Trotman Ltd., 1989., p. 224 from HSDB NIOSH Toxicity Data

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			Measurement / Date / System / Route/Organism / Dose / Effect Skin and Eye Irritation / October 2017 / / eye /human / 50 ppm / mild Skin and Eye Irritation / October 2017 / / eye /rabbit / 100 mg / severe Skin and Eye Irritation / October 2017 / / eye /rabbit / 100 mg/24H / moderate Skin and Eye Irritation / October 2017 / / skin /human / 500 mg rinse / Skin and Eye Irritation / October 2017 / / skin /rabbit / 500 mg open irritation test / mild Skin and Eye Irritation / October 2017 / / skin /rabbit / 100% / moderate Skin Symptoms Redness. Pain. from ILO-ICSC
Benzeneacetic acid (*Phenylacetic Acid*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/999#section=Toxicity NIOSH Toxicity Data Skin and Eye Irritation November 2009 eye /rabbit 100 mg/24H moderate Skin Symptoms Redness. from ILO-ICSC Toxicity Summary HUMAN STUDIES: Inhalation exposure leads to cough, sore throat.Skin exposure leads to redness. from HSDB http://www.thegoodscentscompany.com/data/rw1009911.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Benzeneacetic acid, methyl ester	Y		https://chem.nlm.nih.gov/chemidplus/rn/101-41-7 *Skin/eye irritant*

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
(*Methyl 2-Phenylacetate* *Methyl phenylacetate*)			https://pubchem.ncbi.nlm.nih.gov/compound/7559#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (66.67%): Causes skin irritation [Warning Skin corrosion/irritation]* Skin, Eye, and Respiratory Irritations *A skin irritant.* Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2388 from HSDB http://www.thegoodscentscompany.com/data/rw1008431.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Acute toxicity, dermal (Category 5), H313* *Skin corrosion/irritation (Category 3), H316*
Benzoic acid, 2,4-dihydroxy-3,6-dimethyl-, methyl ester (*Methyl 3-methylorsellinate*)	Y		http://www.thegoodscentscompany.com/data/rw1023372.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* H335
Benzoic acid, 2-hydroxy-, 2-methylpropyl ester (*Isobutyl Salicylate*)	Y		http://www.thegoodscentscompany.com/data/rw1006892.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/37/38 - Irritating to eyes, respiratory system, and skin.*
Benzoic acid, 2-hydroxy-, ethyl ester (*Ethyl salicylate*)	Y		https://chem.nlm.nih.gov/chemidplus/rn/118-61-6 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1001561.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* S 24/25 - Avoid contact with skin and eyes.
Benzophenone		Y	Benzophones-1, -3, -4, -5, -9, and -11

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PRN475.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr219.pdf https://cosmeticsinfo.org/ingredient/benzophenone-1 The Food and Drug Administration (FDA) has approved the use of Benzophenone-3 and Benzophenone-4 as safe and effective, over-the-counter (OTC) sunscreen ingredients. When used as a sunscreen ingredient in the United States, Benzophenone-3 is called Oxybenzone, and may be used at concentrations up to 6%, and Benzophenone-4 is called Sulisobenzone, and may be used at concentrations up to 10%. FDA: Link to Code of Federal Regulations for Benzophenone-3 (Oxybenzone) and Benzophenone-4 (Sulisobenzone) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=352&showFR=1 Benzophenone-3, listed as Oxybenzone, and Benzophenone-4 and -5, listed as Sulisobenzone and Sulisobenzone Sodium, respectively, are included in Annex VII, Part 1 (UV filter which cosmetic products may contain) of the Cosmetics Directive of the European Union. Oxybenzone may be used at concentrations up to 10%, and products containing 0.5% Oxybenzone when used in sunscreen products must be labeled "contains Oxybenzone." Sulisobenzone and Sulisobenzone Sodium may be used at concentrations up to 5% as Sulisobenzone. There are studies that suggest that some sunscreen ingredients, including Oxybenzone may have activity like the hormone, estrogen. Therefore, the European Commission's Scientific Committee for Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) was asked to consider if UV filters as used in sunscreen products have estrogenic effects which have the potential to affect human health. The SCCNFP concluded that UV filters used in sunscreen products allowed in the European market have no estrogenic effects that could potentially affect human health. https://pubchem.ncbi.nlm.nih.gov/compound/3102#section=Exposure-Routes Skin Symptoms Redness. from ILO-ICSC http://www.thegoodscentscompany.com/data/rw1016332.html#tosafty European information : Most important hazard(s): *Xi N - Irritant, Dangerous for the environment.* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.*
Benzyl Alcohol	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr323.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr323.pdf https://chem.nlm.nih.gov/chemidplus/rn/100-51-6 Skin/eye irritant https://pubchem.ncbi.nlm.nih.gov/compound/244#section=Hazards-Identification Signal: Warning GHS Hazard Statements H312 (17.85%): Harmful in contact with skin [Warning Acute toxicity, dermal] Skin, Eye, and Respiratory Irritations A moderate skin and severe eye irritant.

Chemical	Baby Powder	Shower-to-Shower	

Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 399
from HSDB

It is slightly irritating to the skin
International Labour Office. Encyclopedia of Occupational Health and Safety. Vols. I&II. Geneva, Switzerland: International Labour Office, 1983., p. 111
from HSDB

Vapor: Irritating to eyes, nose and throat. Liquid: Irritating to skin & eyes.
U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.
from HSDB

NIOSH Toxicity Data

Measurement	System	Route/Organism	Dose	Effect	Date
Skin and Eye Irritation		skin /human	1%/2D		April 2017
Skin and Eye Irritation		skin /man	16 mg/48H	mild	April 2017
Skin and Eye Irritation		skin /pig	100%	moderate	April 2017
Skin and Eye Irritation		skin /rabbit	100 mg/24H	moderate	April 2017

Skin Symptoms
Redness.
from ILO-ICSC

Toxicity Summary
Toxicity
1250 mg/kg (rat, oral) LD50 400 mg/kg IPR-RAT LD50 2000 mg/kg SKN-RBT LD50 53 mg/kg IVN-RAT LD50 2500 mg/kg ORL-GPG LD50
from DrugBank

HUMAN EXPOSURE AND TOXICITY: Benzyl alcohol has been found to be irritating to the skin at levels 3% or greater. Patch test with 0.65% benzyl alcohol did not produce irritation of the skin. ANIMAL STUDIES: In a primary irritation study 10% benzyl alcohol applied in a 24-hour occlusive patch to the back of eight male albino rabbits did not cause irritation. Undiluted benzyl alcohol was moderately irritating when applied to the depilated skin of guinea pigs for 24 hr.
from HSDB

https://www.ewg.org/guides/substances/641-BENZYLALCOHOL#.W4RkHehKiUk
Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive https://cosmeticsinfo.org/ingredient/benzyl-alcohol The Food and Drug Administration (FDA) includes Benzoic Acid and Sodium Benzoate on its list of direct food substances affirmed as Generally Recognized As Safe (GRAS). The safety of Benzyl Alcohol and Benzyl Benzoate has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on these evaluations, International Fragrance Association (IFRA) Standards have been established. The IFRA standards restrict the use of Benzyl Alcohol and Benzyl Benzoate in fragrances because of potential sensitization. More safety Information: Clinical data indicated that in a few individuals these ingredients produced non-immunologic contact urticaria and non-immunologic immediate contact reactions, characterized by the appearance of wheals, erythema, and pruritis. In one study, 5% Benzyl Alcohol elicited a reaction, and in another study, 2% Benzoic Acid did likewise. Benzyl Alcohol, however, was not a sensitizer at 10%, nor was Benzoic Acid a sensitizer at 2%. Recognizing that the non-immunologic reactions were strictly cutaneous, likely involve a cholinergic mechanism, it was concluded that these ingredients could be used safely at concentrations up to 5%. Additionally, Benzyl Alcohol was considered safe at up to 10% for use in hair dyes. The limited body exposure, the duration of use, and the frequency of use were considered in concluding that the non-immunologic reactions would not be a concern. Link to FDA Code of Federal Regulations and the Federal Register for Benzyl Alcohol https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=benzyl%20alcohol Benzyl Alcohol may be used as a preservative in cosmetics and personal care products marketed in the European Union at a maximum concentration of 1%. Benzoic Acid and its salts and esters are also permitted for use as preservatives in cosmetics and personal care products at a maximum concentration (expressed as the acid) of 2.5% in rinse-off products (except oral care products), 1.7% in oral care products and 0.5% in leave on products (see Annex VI). Benzyl Alcohol and Benzyl Benzoate are also listed in in Annex III of the European Union Cosmetics Directive.When Benzyl Alcohol or Benzyl Benzaote are used as fragrance ingredients, Annex III requires that the presence of these fragrance ingredients be indicated on the label of the product when used at greater than 0.001% in leave-on products, and greater than 0.01% in rinse-off products. The Joint FAO/WHO Expert Committee on Food Additives has established an Acceptable Daily Intake of 0-5 mg/kg for the sum of Benzoic Acid, Potassium and Sodium Benzoate: http://www.inchem.org/documents/jecfa/jecmono/40abcj02.htm
Benzyl Benzoate	Y	Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR574.pdf https://pubchem.ncbi.nlm.nih.gov/compound/2345#section=Fire-Hazard Skin, Eye, and Respiratory Irritations Benzyl benzoate is relatively nontoxic but may irritate the skin and eyes.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994., p. 1615 from HSDB Skin Symptoms MAY BE ABSORBED! Dry skin. Redness. from ILO-ICSC https://www.ewg.org/guides/substances/642-BENZYLBENZOATE#.W4RnX-hKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive https://cosmeticsinfo.org/ingredient/benzyl-benzoate SEE BENZYL ALCOHOL
Benzyl Salicylate	Y	Y	https://pubchem.ncbi.nlm.nih.gov/compound/8363#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements H317 (95.53%): May cause an allergic skin reaction [Warning Sensitization, Skin] H319 (72.34%): Causes serious eye irritation [Warning Serious eye damage/eye irritation] NIOSH Toxicity Data

Measurement	Date	System	Route/Organism	Dose	Effect
Skin and Eye Irritation	April 2015		skin /human	2%/2D	

https://www.ewg.org/guides/substances/645-BENZYLSALICYLATE#.W4RwP-hKiUk
Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive

The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive

https://cosmeticsinfo.org/ingredient/benzyl-salicylate-0
The Food and Drug Administration (FDA) has approved the use of Benzyl Salicylate as a flavoring agent for direct addition to food. The safety of Benzyl Salicylate has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Benzyl Salicylate in fragrances because of potential sensitization.

More safety Information:
See the FDA Code of Federal Regulations for Benzyl Salicylate:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=172.515

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Benzyl Salicylate does not present a safety concern at current levels of intake when used as a flavoring agent. http://www.inchem.org/documents/jecfa/jeceval/jec_215.htm The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Benzyl Salicylate and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring substance. In Europe, Benzyl Salicylate is included on the list of "allergenic" substances. The European Cosmetics Directive requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Benzyl Salicylate must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0012 http://www.thegoodscentscompany.com/data/rw1001792.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* *R 43 - May cause sensitisation by skin contact.* S 24 - Avoid contact with skin. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Skin sensitisation (Category 1), H317
Boswellia Carterii Oil (*Oils, olibanum Frankincense oil*)	Y		No Data http://www.thegoodscentscompany.com/data/es1004051.html#tosafty European information : Most important hazard(s): Xn - Harmful. R 10 - Flammable. *R 20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* R 42/43 - May cause sensitization by inhalation and skin contact. S 24/25 - Avoid contact with skin and eyes.
Butanoic acid, ethyl ester (*Ethyl n-butyrate* *Ethyl butanoate*)	Y		https://chem.nlm.nih.gov/chemidplus/rn/105-54-4 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1004792.html#tosafty European information : Most important hazard(s): Xi - Irritant R 10 - Flammable. R 36/37/38 - Irritating to eyes, respiratory system, and skin. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Butanoic acid, pentyl ester (*Amyl Butyrate*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/10890#section=Health-Hazard

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			Excerpt from ERG Guide 130 [Flammable Liquids (Water-Immiscible / Noxious)]: May cause toxic effects if inhaled or absorbed through skin. Inhalation or contact with material may irritate or burn skin and eyes. Fire will produce irritating, corrosive and/or toxic gases. Vapors may cause dizziness or suffocation. Runoff from fire control or dilution water may cause pollution. (ERG, 2016) from CAMEO Chemicals http://www.thegoodscentscompany.com/data/rw1004151.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/37/38 - Irritating to eyes, respiratory system, and skin.
Camphor	Y		https://pubchem.ncbi.nlm.nih.gov/compound/2537#section=Hazards-Identification Signal: Danger GHS Hazard Statements H312 (10.82%): Harmful in contact with skin [Warning Acute toxicity, dermal] H315 (16.04%): Causes skin irritation [Warning Skin corrosion/irritation] Health Hazard Excerpt from ERG Guide 133 [Flammable Solids]: Fire may produce irritating and/or toxic gases. Contact may cause burns to skin and eyes. Contact with molten substance may cause severe burns to skin and eyes. Runoff from fire control may cause pollution. (ERG, 2016) from CAMEO Chemicals Skin, Eye, and Respiratory Irritations The substance is irritating to the eyes, the skin, and the respiratory tract. International Program on Chemical Safety/ Commission of the European Union; International Chemical Safety Card on Camphor. (May 2003). Available from, as of June 30, 2014: http://www.inchem.org/documents/icsc/icsc/eics1021.htm from HSDB Health Effects Irritation-Eye, Nose, Throat, Skin---Moderate (HE15) Acute Toxicity---short-term high hazard effects (HE4) CNS Effects (HE7) from OSHA Chemical Sampling Information Symptoms Irritation of eyes, skin, mucous membrane; nausea, vomiting, diarrhea; headache, dizziness, excitement, epileptiform convulsions; cough, sore throat; Ingestion Acute: Burning sensation in throat and chest; GI symptoms; confusion, seizures, unconsciousness; Skin Absorption; Hepatotoxicity without GI symptoms. from OSHA Chemical Sampling Information irritation eyes, skin, mucous membrane; nausea, vomiting, diarrhea; headache, dizziness, excitement, epileptiform convulsions from The National Institute for Occupational Safety and Health (NIOSH) Skin Symptoms Redness. from ILO-ICSC https://cosmeticsinfo.org/ingredient/camphor-0

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			The Food and Drug Administration (FDA) includes Camphor in its list of flavoring agents and related substances that are permitted for direct addition to food. Camphor is also approved for use as an active ingredient in Over-The-Counter (OTC) external analgesics, topical antitussive drug products and in anorectal products at concentrations of 0.1 to 3%. More safety Information: The International Programme on Chemical Safety has developed a monograph on the uses and potential effects of Camphor. Fairly large oral doses of Camphor are needed before adverse effects are observed. Carcinogenicity tests have been negative and Camphor is not mutagenic in bacteria. http://www.inchem.org/documents/pims/pharm/camphor.htm Natural Flavoring Substances: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.510&SearchTerm=camphor Antitussive Active Ingredients https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=341.14&SearchTerm=camphor Analgesic, Anesthetic, and Antipruritic Active Ingredients https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=346.16&SearchTerm=camphor Camphor may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 Health Canada permits the use of Camphor in cosmetics and personal care products at concentrations less than or equal to 3%. https://www.canada.ca/en/health-canada/services/cosmetics.html http://www.thegoodscentscompany.com/data/rw1056901.html#tosafty European information : Most important hazard(s): Xn - Harmful. R 20/21/22 - Harmful by inhalation, in contact with skin and if swallowed. R 36/37/38 - Irritating to eyes, respiratory system, and skin. R 40 - Limited evidence of a carcinogenic effect.
Caproic Acid	Y		https://chem.nlm.nih.gov/chemidplus/rn/142-62-1 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/8892#section=Hazards-Identification Signal: Danger GHS Hazard Statements *H311 (23.6%): Toxic in contact with skin [Danger Acute toxicity, dermal]* *H314 (100%): Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]* Health Hazard Harmful if swallowed, inhaled, or absorbed through skin. Material is extremely destructive to tissue of mucous membranes and upper respiratory tract, eyes and skin. Inhalation may be fatal as a result of spasm, inflammation and edema of the larynx and bronchia, chemical pneumonitis and pulmonary edema. Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea and vomiting. (USCG, 1999)

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

<table>
<tr><th>Chemical</th><th>Baby Powder</th><th>Shower-to-Shower</th><th></th></tr>
<tr><td></td><td></td><td></td><td>
from CAMEO Chemicals

NIOSH Toxicity Data
<table>
<tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr>
<tr><td>Skin and Eye Irritation</td><td></td><td>eye /rabbit</td><td>750 µg</td><td>severe</td><td>October 2015</td></tr>
<tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>10 mg/24H open irritation test</td><td>mild</td><td>October 2015</td></tr>
<tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>465 mg open irritation test</td><td>mild</td><td>October 2015</td></tr>
</table>
Skin Symptoms
Redness. Pain.
from ILO-ICSC

http://www.thegoodscentscompany.com/data/rw1008541.html#tosafty
European information :
Most important hazard(s):
C - Corrosive.
R 20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.
R 34 - Causes burns.
S 24/25 - Avoid contact with skin and eyes.
S 28 - After contact with skin, wash immediately with plenty of water.
</td></tr>
<tr><td>Carum Carvi (Caraway) Fruit Oil</td><td>Y</td><td></td><td>
https://chem.nlm.nih.gov/chemidplus/rn/8000-42-8
Skin/eye irritant

http://www.thegoodscentscompany.com/data/es1028851.html#tosafty
European information :
Most important hazard(s):
Xi N - Irritant, Dangerous for the environment.
R 36/37/38 - Irritating to eyes, respiratory system, and skin.
R 43 - May cause sensitisation by skin contact.
</td></tr>
<tr><td>Cedrol</td><td>Y</td><td></td><td>
https://pubchem.ncbi.nlm.nih.gov/compound/65575#section=GHS-Classification
Skin, Eye, and Respiratory Irritations
...produced slight /skin/ irritation.
Opdyke, D.L.J. (ed.). Monographs on Fragrance Raw Materials. New York: Pergamon Press, 1979., p. 205
from HSDB

http://www.thegoodscentscompany.com/data/rw1003031.html#tosafty
European information :
Most important hazard(s):
Xi - Irritant
R 36/37/38 - Irritating to eyes, respiratory system, and skin.
S 24/25 - Avoid contact with skin and eyes.
</td></tr>
</table>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
Cedrus Atlantica (Cedarwood) Bark Oil	Y		https://chem.nlm.nih.gov/chemidplus/rn/8023-85-6 *Skin/eye irritant* https://www.ewg.org/guides/substances/1083-CEDRUSATLANTICAATLASCEDARBARKOIL#.W4SHeOhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Frangrance allergens in cosmetics (2011) - EU Cosmetics Directive
Cinnamal (*Cinnamaldehyde*)	Y		https://chem.nlm.nih.gov/chemidplus/rn/104-55-2 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/637511#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (100%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Health Hazard ACUTE/CHRONIC HAZARDS: Exposure to this chemical may cause irritation of the skin, eyes, upper respiratory tract and mucous membranes. (NTP, 1992) from CAMEO Chemicals SYMPTOMS: ACUTE/CHRONIC HAZARDS: This chemical may be harmful by inhalation, ingestion or skin absorption. It may cause irritation of the skin, eyes, upper respiratory tract, and mucous membranes. When heated to decomposition it may emit toxic fumes of carbon monoxide and carbon dioxide. (NTP, 1992) from CAMEO Chemicals Skin, Eye, and Respiratory Irritations No primary dermal irritation was observed in human subjects exposed for 48 hours to a solution of a 3% active ingredient, while severe primary dermal irritation was observed in human subjects after exposure to 8% active ingredient. USEPA, Office of Pesticide Programs/ Ombudsman, Biopesticides and Pollution Prevention Division: Active Ingredient Fact Sheet for Cinnamaldehyde (040506) (December 2000). Available from, as of July 13, 2009: http://www.epa.gov/pesticides/biopesticides/ingredients/index_p-s.htm from HSDB Toxicological Information Health Effects Irritation-Eyes, Nose, Throat, Skin---Moderate (HE15); Allergic Contact Dermatitis (HE3) from OSHA Chemical Sampling Information Symptoms Irritation of eyes, skin, nose, throat; skin rash, itching; anaphylaxis (one case); INGES. ACUTE: Sore throat from OSHA Chemical Sampling Information Target Organs Eyes, skin, respiratory system from OSHA Chemical Sampling Information https://www.ewg.org/guides/substances/1258-CINNAMAL#.W4SOauhKiUk

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive https://cosmeticsinfo.org/ingredient/cinnamal-0 The Food and Drug Administration (FDA) includes Cinnamal on its list of substances considered Generally Recognized As Safe (GRAS) for use as a synthetic flavoring substance. The safety of Cinnamal has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Cinnamal in fragrances because it of potential sensitization. More safety Information: Link to FDA Code of Federal Regulations for Cinnamal: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=cinnamaldehyde The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Cinnamal does not present a safety concern at current levels of intake when used as a flavoring agent. Link to the JECFA safety evaluation of Cinnamal: http://www.inchem.org/documents/jecfa/jeceval/jec_418.htm The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Cinnamal and determined that it was Generally Recognized as Safe (GRAS) for use a flavoring substance. In Europe, Cinnamal is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Cinnamal must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1002632.html#tosafty European information : Most important hazard(s): Xn - Harmful. R 21/41 - Harmful in contact with skin, risk of serious damage to eyes. *R 38 - Irritating to skin.* *R 43 - May cause sensitisation by skin contact.* S 02 - Keep out of the reach of children. S 24 - Avoid contact with skin. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Skin irritation (Category 2), H315 Skin sensitisation (Category 1), H317
Cinnamyl Alcohol (*3-Phenyl-2-propen-1-ol*)	Y	Y	https://chem.nlm.nih.gov/chemidplus/rn/104-54-1 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/5315892#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			H317 (96.97%): May cause an allergic skin reaction [Warning Sensitization, Skin] https://cosmeticsinfo.org/ingredient/cinnamyl-alcohol-0 The Food and Drug Administration (FDA) includes Cinnamyl Alcohol on its list of flavoring agents permitted for direct addition to food. The safety of Cinnamyl Alcohol has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Cinnamyl in fragrances because of potential sensitization. More safety Information: Link to FDA Code of Federal Regulations for Cinnamyl Alcohol: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=cinnamyl%20alcohol The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Cinnamyl Alcohol does not present a safety concern at current levels of intake when used as a flavoring agent. Link to the JECFA safety evaluation of Cinnamyl Alcohol: http://www.inchem.org/documents/jecfa/jeceval/jec_422.htm The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Cinnamyl Alcohol and determined that it was Generally Recognized as Safe (GRAS) for use as a flavoring substance. In Europe, Cinnamyl Alcohol is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Cinnamyl Alcohol must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1003292.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *R 43 - May cause sensitisation by skin contact.* S 24 - Avoid contact with skin. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317*
Citral (*Geranial)*	Y		https://chem.nlm.nih.gov/chemidplus/rn/5392-40-5 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/638011#section=Hazards-Identification Signal: Danger GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (23.56%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Health Hazard

Chemical	Baby Powder	Shower-to-Shower	

SYMPTOMS: Symptoms of exposure to this compound may include contact dermatitis. ACUTE/CHRONIC HAZARDS: This compound is a local irritant. When heated to decomposition it emits acrid smoke and fumes. (NTP, 1992)
from CAMEO Chemicals

Skin, Eye, and Respiratory Irritations

Irritant effect of 19 oils & 20 synthetic perfumes used in cosmetics were tested on skin of 50 male volunteers. Citral @ 32% concn was the most irritating of perfumes in human patch test.
Motoyoshi k et al; Cosmet Toilet 94: 41 (197
from HSDB

Irritating to skin.
European Chemicals Bureau; IUCLID Dataset, Citral (CAS No. 5392-40-5). Available from, as of January 22, 2007: http://esis.jrc.ec.europa.eu/
from HSDB

A cumulative irritation study was carried out on 8 volunteers. Patches were placed on the back daily, removed at 24 hr and read and them replaced with a fresh patch, over a period of 21 days. /Citral concentrations tested included 1, 4 and 8% in petrolatum./ The 8 % concentration was found to be a marginal irritant.
European Chemicals Bureau; IUCLID Dataset, Citral (CAS No. 5392-40-5). Available from, as of January 22, 2007: http://esis.jrc.ec.europa.eu/
from HSDB

During an investigation of an outbreak of dermatitis following the introduction of a lemon-scented detergent, citral was shown by patch tests to be a strong primary irritant if applied in association with heat; 10% citral induced slight responses at 23 deg C and pronounced responses at 43 deg C.
Abstract: PubMed
Rothenborg HW et al; Contact Dermatitis 3 (1): 37 (1977)
from HSDB

NIOSH Toxicity Data

Measurement	Date	System	Route/Organism	Dose	Effect
Skin and Eye Irritation	October 2017		skin /guinea pig	1%/48H	moderate
Skin and Eye Irritation	October 2017		skin /guinea pig	100 mg/24H	severe
Skin and Eye Irritation	October 2017		skin /human	2%/2D	
Skin and Eye Irritation	October 2017		skin /human	40 mg/24H	mild
Skin and Eye Irritation	October 2017		skin /man	16 mg/48H	severe
Skin and Eye Irritation	October 2017		skin /pig	50 mg/48H	severe

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	

Skin and Eye Irritation	October 2017		skin /rabbit	500 mg/24H	moderate
Skin and Eye Irritation	October 2017		skin /rabbit	100 mg/24H	severe
Skin and Eye Irritation	October 2017		skin /woman	2%	

Skin Symptoms

Redness.
from ILO-ICSC

Toxicity Summary

Citral was rapidly absorbed from the gastro -intestinal tract. Much of an applied dermal dose was lost due to its extreme volatility, but the citral remaining on the skin was fairly well absorbed. Citral was rapidly metabolized and excreted as metabolites. Urine was the major route of elimination. Acute toxicity of this chemical is low in rodents because the oral or dermal LD50 values were more than 1000 mg/kg. This chemical is irritating to skin and not irritating to eyes in rabbits. There is some evidence that this chemical is a human skin sensitizer.
OECD; Screening Information Data Set for Citral, CAS # 5392-40-5 (2004). Available from, as of January 22, 2007: http://www.inchem.org/pages/sids.html

https://www.ewg.org/guides/substances/1279-CITRAL#.W4SeRehKiUk

Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive

The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive

https://cosmeticsinfo.org/ingredient/citral-0

The Food and Drug Administration (FDA) includes Citral in its list of substances considered Generally Recognized As Safe (GRAS) as a synthetic flavoring substance. The safety of Citral has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Citral in fragrances because of potential sensitization.

More safety Information:
Link to FDA Code of Federal Regulations for Citral:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=citral

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an Acceptable Daily Intake of up to 0.5 mg/kg body weight Citral when used as a flavoring agent.

Link to the JECFA safety evaluation of Citral: http://www.inchem.org/documents/jecfa/jeceval/jec_432.htm

The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Citral and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring substance. In Europe, Citral is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			Citral must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1003432.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 38 - Irritating to skin.* *R 43 - May cause sensitisation by skin contact.* S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317*
Citronellyl Nitrile (*3,7-Dimethyloct-6-enenitrile*)		Y	http://www.thegoodscentscompany.com/data/rw1008932.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
Citrus Aurantifolia (Lime) Oil	Y		https://chem.nlm.nih.gov/chemidplus/rn/8008-26-2 *Skin/eye irritant (Lime Oil)* https://chem.nlm.nih.gov/chemidplus/rn/90063-52-8 (Citrus Aurantifolia Extract)
Commiphora Myrrha Oil		Y	http://www.thegoodscentscompany.com/data/es1002061.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/38 - Irritating to skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317*
Commiphora Myrrha Resin	Y		http://www.thegoodscentscompany.com/data/rs1008771.html European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.*
Coriandrum Sativum (Coriander) Fruit Oil (*Cilantro*)	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/8008-52-4 *Skin/eye irritant* https://www.ewg.org/guides/substances/1504-CORIANDRUMSATIVUMCORIANDEROIL#.W37RTehKiUk Component: LINALOOL Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive Component: LINALOOL

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Component: GERANIOL Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive Component: GERANIOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41. Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Pia Forsström, Ann-Marie Wennberg, Ann-Therese Karlberg & Mihály Matura. 2009. Air oxidation increases skin irritation from fragrance terpenes. Contact dermatitis 60(1), 32-40. Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1. Component: LINALOOL This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8. Component: D-LIMONENE Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/es1003771.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* *R 43 - May cause sensitisation by skin contact.*
Coumarin	Y	Y	https://pubchem.ncbi.nlm.nih.gov/compound/323#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H317 (90.48%): May cause an allergic skin reaction [Warning Sensitization, Skin]* NIOSH Toxicity Data

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	

Measurement	System	Route/Organism	Dose	Effect	Date
Skin and Eye Irritation		skin /human	5%/2D		June 2017
Skin and Eye Irritation		skin /man	5%		June 2017

Skin Symptoms
MAY BE ABSORBED! Redness. Pain.
from ILO-ICSC

https://www.ewg.org/guides/substances/1528-COUMARIN#.W37OeehKiUk
Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive

The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive

http://www.thegoodscentscompany.com/data/rw1003832.html#tosafty
European information :
Most important hazard(s):
Xn - Harmful.
R 43 - May cause sensitisation by skin contact.
S 24/25 - Avoid contact with skin and eyes.

https://cosmeticsinfo.org/ingredient/coumarin-0
The Food and Drug Administration (FDA) does not permit Coumarin to be directly added to food. The safety of Coumarin has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Coumarin in fragrances because of potential sensitization.

In 2008, the International Fragrance Association (IFRA) issued a position statement that states that the fragrance industry is not aware of any reported systemic adverse health effects with regard to topically applied Coumarin.

More safety Information:
Link to the FDA Code of Federal Regulations for Coumarin:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=189.130&SearchTerm=coumarin

In Europe, Coumarin is included on the list of "allergenic" substances. The European Cosmetics Directive requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Coumarin must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin

Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			The European Commission's Scientific Committee on Consumer Products (SCCP) evaluated Coumarin as a fragrance allergen and concluded that this ingredient was frequently reported and a well-recognized consumer allergen. Link to the European Commission's SCCP opinion concerning Coumarin: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf Coumarin was evaluated by IARC and was not classifiable as to its carcinogenicity in humans. Link to the IARC monograph for Coumarin: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono77-9.pdf https://monographs.iarc.fr/preamble-to-the-iarc-monographs-amended-january-2006/preamble-to-the-iarc-monographs-13/
Cuminum Cyminum (Cumin) Seed Oil (*Cumin Oil*)	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/8014-13-9 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/es1016101.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/37/38 - Irritating to eyes, respiratory system, and skin.*
Cyclamen Aldehyde	Y	Y	https://chem.nlm.nih.gov/chemidplus/rn/startswith/103-95-7 *Skin/eye irritant* https://www.ewg.org/guides/substances/1563-CYCLAMENALDEHYDE#.W37KcehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance lacks data on contact allergy in humans. Opinion on Frangrance allergens in cosmetics (2011) - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/rw1004112.html European information : Most important hazard(s): *Xi N - Irritant, Dangerous for the environment.* *R 38 - Irritating to skin.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Decanal	Y		https://pubchem.ncbi.nlm.nih.gov/compound/8175#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (25.17%): Causes skin irritation [Warning Skin corrosion/irritation]* Health Hazard *On direct contact can produce eye and skin irritation;* low general toxicity. (USCG, 1999) from CAMEO Chemicals https://chem.nlm.nih.gov/chemidplus/rn/startswith/112-31-2 Skin/eye irritant https://www.ewg.org/guides/substances/1689-DECANAL#.W37It-hKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance lacks data on contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

<table>
<tr><th>Chemical</th><th>Baby Powder</th><th>Shower-to-Shower</th><th></th></tr>
<tr><td></td><td></td><td></td><td>http://www.thegoodscentscompany.com/data/rw1000172.html#tosafty
European information :
Most important hazard(s):
Xi N - Irritant, Dangerous for the environment.
R 38 - Irritating to skin.

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Skin irritation (Category 2), H315</td></tr>
<tr><td>Diethyl Phthalate</td><td></td><td>Y</td><td>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR758.pdf
https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PRN475.pdf
https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr200.pdf

https://pubchem.ncbi.nlm.nih.gov/compound/6781#section=Hazards-Identification
Signal: Danger
GHS Hazard Statements
H315 (22.62%): Causes skin irritation [Warning Skin corrosion/irritation]

Skin, Eye, and Respiratory Irritations
DEP is slightly irritating to the eye and skin.
Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. V6 824
from HSDB

NIOSH Toxicity Data

<table>
<tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr>
<tr><td>Skin and Eye Irritation</td><td></td><td>eye /rabbit</td><td>112 mg</td><td></td><td>October 2017</td></tr>
<tr><td>Skin and Eye Irritation</td><td></td><td>skin /human</td><td>2%/3W- intermittent</td><td>mild</td><td>October 2017</td></tr>
</table>

https://chem.nlm.nih.gov/chemidplus/rn/startswith/84-66-2
Skin/eye irritant

https://cosmeticsinfo.org/ingredient/dimethyl-phthalate-diethyl-phthalate-and-dibutyl-phthalate-0
More safety Information:
The U.S. Food and Drug Administration(FDA) has stated that, at the present time, it does not have evidence that phthalates as used in cosmetics pose a safety risk. FDA noted that an expert panel convened from 1998 to 2000 by the National Toxicology Program (NTP), headquartered at the National Institute of Environmental Health Sciences (NIEHS), concluded that reproductive risks from exposure to phthalates from all sources were minimal to negligible in most cases.

FDA has reviewed all of the available safety and toxicity data for phthalates, including biomonitoring data from the Centers for Disease Control (CDC) measuring levels in human urine, as well as the CIR conclusions based on reviews in 1985 and 2002. None of the data reviewed by FDA established an association between the use of phthalates in cosmetic products and a health risk.</td></tr>
</table>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
			Based on this information, FDA determined that there wasn't a sound, scientific basis to support taking regulatory action against cosmetics containing phthalates. https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128250.htm FDA includes Dimethyl Phthalate (DMP), Diethyl Phthalate (DEP) and Dibutyl phthalate (DBP) on its list of indirect food additives. For example, all three ingredients may be used in adhesives that contact food, DEP and DBP may be used in food contact polymers, and DBP may be used as a slimicide in paper and paperboard used for food packaging. DMP and DEP may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union . DBP is not permitted for use in cosmetics and personal care products in the European Union (see Annex II). DBP was banned in Europe because all substances classified as carcinogenic, mutagenic or toxic to reproduction (categories 1 and 2) under EU chemical hazard classification legislation are automatically banned from use in cosmetics and personal care products, regardless of use concentration. The low exposure to DBP in cosmetics and personal care products was not considered when this ban went into effect. As mentioned earlier, the CIR Expert Panel estimated that exposure to DBP from using cosmetic and personal care products would be well below the dose that did not cause any reproductive and developmental effects in animals. Therefore, the CIR Expert Panel did not see the need to change their original conclusion that DBP was safe as used in cosmetic products. Similar, when considering exposure European experts, (SCCNFP) agree with CIR and concluded in their 2002 opinion that "the safety profile of diethyl phthalate supports its use in cosmetic products at current levels." This opinion was confirmed in a second opinion in 2004. Learn more about EU Cosmetic Regulation: http://ec.europa.eu/growth/tools-databases/cosing/ Learn more about SCCNFP's 2004 opinion on Dibutyl phthalate: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out287_en.pdf It's a myth that phthalates are 'hidden' in fragrances Fragrances are usually composed of numerous individual substances that are blended together to achieve the desired scent. If a cosmetic product contains a fragrance, this is labelled using the word 'fragrance' or 'parfum' in the ingredients list rather than having to list out all of the individual components. This is legally allowed by the strict cosmetic safety laws and is common practice around the world. It is, however, not a way of 'hiding' ingredients as is sometimes, wrongly, claimed. All of the ingredients that make up the fragrance are still assessed very carefully as part of the overall product safety assessment. DEP and DMP may legally and safely be used as part of the fragrance mix. No substances banned from use as cosmetic ingredients are allowed to be used as components of cosmetic fragrances. Can phthalates be used in personal care products intended for use by children? Phthalate ingredients can be used in personal care products intended for use by children - e.g., in lotions, shampoos, etc. Like personal care products intended for use by adults, the only phthalate that is sometimes present in personal care products intended for children and infants is DEP. The safety of DEP is well accepted among the scientific community. To date, all scientific reviews around the world by key scientific experts and governmental agencies have concluded that DEP is safe for use in cosmetics and personal care products under the current conditions of use. DEP has been reviewed by the U.S. Cosmetic Ingredient Review (CIR) Expert Panel and the European Commission's independent scientific expert committee (the Scientific Committee on Consumer Safety, SCCS and formerly known as the

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			SCCNFP). Both expert scientific groups have approved the safe use of DEP in cosmetic products and have not deemed it necessary to impose any specific warnings or restrictions for its use. http://www.thegoodscentscompany.com/data/rw1004351.html#tosafty European information : Most important hazard(s): *Xn - Harmful.* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.*
Dihydrocitronellol (*3,7-Dimethyloctan-1-ol*)		Y	https://pubchem.ncbi.nlm.nih.gov/compound/7792#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* https://chem.nlm.nih.gov/chemidplus/rn/startswith/106-21-8 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1000592.html#tosafty European information : Most important hazard(s): *Xi N - Irritant, Dangerous for the environment.* *R 36/38 - Irritating to skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Dimethylhydroquinone (*1,4-Dimethoxybenzene*)	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/150-78-7 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/9016#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* NIOSH Toxicity Data

Measurement	System	Route/Organism	Dose	Effect	Date
Skin and Eye Irritation		skin /guinea pig	40%/24H	moderate	April 2015
Skin and Eye Irritation		skin /rabbit	6 gm/12D- intermittent	mild	April 2015
Skin and Eye Irritation		skin /rabbit	500 mg/24H	moderate	April 2015

http://www.thegoodscentscompany.com/data/rw1004451.html#tosafty

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Ethyl 3-methyl-3-phenyloxirane-2-carboxylate (*Ethyl Methylphenylglycidate*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/6501#section=Hazards-Identification Signal: Warning GHS Hazard Statements *H317 (77.27%): May cause an allergic skin reaction [Warning Sensitization, Skin]* http://www.thegoodscentscompany.com/data/rw1001602.html#tosafty European information : GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Ethyl Benzoate	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr578.pdf https://pubchem.ncbi.nlm.nih.gov/compound/7165#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (72.29%): Causes skin irritation [Warning Skin corrosion/irritation]* https://cosmeticsinfo.org/ingredient/ethyl-benzoate The Food and Drug Administration (FDA) permits Methyl Benzoate, Ethyl Benzoate, Propyl Benzoate, Isopropyl Benzoate and Isobutyl Benzoate to be used as flavoring agents for direct addition to food. Butyl Benzoate is permitted for use as an indirect food additive as a component of adhesives. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=benzyl%20benzoate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=175.105 The European Union lists salts and esters of benzoic acid (including Methyl Benzoate, Ethyl Benzoate, Propyl Benzoate, Butyl Benzoate, Isopropyl Benzoate and Isobutyl Benzoate) as preservatives that may be safety used in cosmetics at concentrations up to 0.5% (See Annex IV). Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1004771.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
Ethyl heptoate	Y		http://www.thegoodscentscompany.com/data/rw1009172.html#tosafty European information : Most important hazard(s):

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			Xi - Irritant *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
Ethyl Vanillin	Y		https://pubchem.ncbi.nlm.nih.gov/compound/8467#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (14.69%): Causes skin irritation [Warning Skin corrosion/irritation]* Health Hazard ACUTE/CHRONIC HAZARDS: Toxic. May cause irritation on contact. (NTP, 1992) from CAMEO Chemicals Skin, Eye, and Respiratory Irritations *A human skin irritant.* Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 1610 from HSDB Toxicity Summary HUMAN EXPOSURE AND TOXICITY: Research in humans showed that ethyl vanillin had no significant effect on the activity of five human CYP450 enzymes with concentration ranged from 8 to 128 uM. A 2% concentration of ethyl vanillin caused mild irritation on the skin of humans after 48 hours of direct contact. ANIMAL STUDIES from HSDB https://chem.nlm.nih.gov/chemidplus/rn/startswith/121-32-4 Skin/eye irritant https://www.ewg.org/guides/substances/2100-ETHYLVANILLIN#.W33GAehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/rw1002652.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Eugenol	Y	Y	https://pubchem.ncbi.nlm.nih.gov/compound/3314#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H317 (99.88%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Health Hazard

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			SYMPTOMS: *This compound is a primary irritant and sensitizer and can cause contact dermatitis. Irritation of the skin, eyes and respiratory tract occurs*. Skin contact may cause an inflammatory reaction on the skin. Prolonged or repeated skin contact may cause allergic dermatitis.. Skin sensitization may also occur. (NTP, 1992) from CAMEO Chemicals https://chem.nlm.nih.gov/chemidplus/rn/startswith/97-53-0 *Skin/eye irritant* https://cosmeticsinfo.org/ingredient/eugenol-0 The Food and Drug Administration (FDA) includes clove and its derivatives, including Eugenol, on its list of substances affirmed as Generally Recognized As Safe (GRAS) as direct food substances. The safety of Eugenol has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Eugenol in fragrances because of potential sensitization. More safety Information: Link to FDA Code of Federal Regulations for Eugenol: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1257&SearchTerm=eugenol The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an Acceptable Daily Intake for Eugenol of up to 2.5 mg/kg body weight when used as a flavoring agent. Link to the JECFA safety evaluation of Eugenol: http://www.inchem.org/documents/jecfa/jeceval/jec_841.htm The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Eugenol and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring agent. In Europe, Eugenol is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Eugenol must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1004992.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* *R 42/43 - May cause sensitization by inhalation and skin contact.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin sensitization (Category 1), H317*
Formic acid, phenylmethyl ester (*Benzyl formate*)	Y		http://www.thegoodscentscompany.com/data/rw1012591.html#tosafty European information : Most important hazard(s): Xn - Harmful. R 21/22 - Harmful in contact with skin and if swallowed. S 24 - Avoid contact with skin.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Acute toxicity, Dermal (Category 3), H311
Gamma-Nonalactone (*5-Pentyloxolan-2-one*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7710#section=Hazards-Identification Signal: Warning GHS Hazard Statements *H315 (50%): Causes skin irritation [Warning Skin corrosion/irritation]* Skin, Eye, and Respiratory Irritations *A skin irritiant.* Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 979 from HSDB https://chem.nlm.nih.gov/chemidplus/rn/startswith/104-61-0 Skin/eye irritant http://www.thegoodscentscompany.com/data/rw1000532.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
Gamma-Undecalactone	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/104-67-6 Skin/eye irritant https://pubchem.ncbi.nlm.nih.gov/compound/7714#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (19.3%): Causes skin irritation [Warning Skin corrosion/irritation]* ratio from companies that provide hazard codes. Only hazard codes with percentage values above 10% are shown. http://www.thegoodscentscompany.com/data/rw1000822.html#tosafty GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Geraniol	Y	Y	https://chem.nlm.nih.gov/chemidplus/rn/startswith/106-24-1 Skin/eye irritant https://pubchem.ncbi.nlm.nih.gov/compound/637566#section=Hazards-Identification Signal: Danger GHS Hazard Statements *H315 (98.89%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (99.59%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Skin, Eye, and Respiratory Irritations

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			A severe human skin irritant. Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 1440 from HSDB https://www.ewg.org/guides/substances/2340-GERANIOL#.W32bDehKiUk Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive https://cosmeticsinfo.org/ingredient/geraniol-0 The Food and Drug Administration (FDA) includes Geraniol on its lists of flavoring substance considered Generally Recognized As Safe (GRAS). The safety of Geraniol has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Geraniol in fragrances because of potential sensitization. More safety Information: Link to FDA Code of Federal Regulations for Geraniol: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=geraniol The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Geraniol does not present a safety concern at current levels of intake when used as a flavoring agent. Link to the JECFA safety evaluation of Geraniol: http://www.inchem.org/documents/jecfa/jeceval/jec_898.htm The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Geraniol and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring substances. In Europe, Geraniol is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Geraniol must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1006992.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. *R 43 - May cause sensitisation by skin contact.* *S 24/25 - Avoid contact with skin and eyes..* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317*
Geranyl Acetate	Y		https://pubchem.ncbi.nlm.nih.gov/compound/1549026#section=Safety-and-Hazards Signal: Warning

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			GHS Hazard Statements H315 (15.29%): Causes skin irritation [Warning Skin corrosion/irritation] H317 (15.29%): May cause an allergic skin reaction [Warning Sensitization, Skin] Health Hazard SYMPTOMS: Symptoms of exposure to this compound *include skin and eye irritation*.. ACUTE/CHRONIC HAZARDS: This compound can cause eye damage and skin irritation.. (NTP, 1992) from CAMEO Chemicals Skin, Eye, and Respiratory Irritations In human patch test, geraniol @ 32% concn was severely irritating & geranyl acetate mildly irritating. Motoyoski et al; Cosmet Toiletries 94(8): 41 (1979) from HSDB https://chem.nlm.nih.gov/chemidplus/rn/startswith/105-87-3 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1030092.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Heliotropine (*piperonal*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/8438#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H317 (96.36%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Health Hazard SYMPTOMS: Symptoms of exposure to this compound may include depression of the central nervous system and local irritation. ACUTE/CHRONIC HAZARDS: This compound is an irritant. (NTP, 1992) from CAMEO Chemicals TSCA Test Submissions Piperonal (CAS # 120-57-0) was evaluated for primary dermal irritation. The test substance was applied to the cuff of 8 guinea pigs (sex and strain not indicated) at a dose range of 0.25-1.0 mg/kg. Strong skin irritation was evident at 24 hours with slight to gross edema and slight to severe erythema. At 48 hours, slight to moderate edema and erythema was found with eschar formation and necrotic area over part or all of the patch. At 1-week and 2-week observation, desquamation and alopecia was evident. EASTMAN KODAK CO; Letter From Eastman Kodak Co To USEPA Submitting Enclosed Material Safety Data Sheet and Toxicity Report on Piperonal with Attachments; 10/22/91; EPA Doc No. 86-920000085; Fiche No. OTS0533448 from HSDB

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			https://chem.nlm.nih.gov/chemidplus/rn/startswith/120-57-0 Skin/eye irritant http://www.thegoodscentscompany.com/data/rw1005891.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/37/38 - Irritating to eyes, respiratory system, and skin. *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Hexamethylindanopyran (*Galaxolide*)	Y	Y	*Galaxolide* https://chem.nlm.nih.gov/chemidplus/rn/startswith/1222-05-5 Skin/eye irritant https://www.ewg.org/guides/substances/2-GALAXOLIDE#.W32QNuhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/rw1104661.html#tosafty European information : Most important hazard(s): Xi N - Irritant, Dangerous for the environment. *R 38 - Irritating to skin.* *S 24 - Avoid contact with skin.*
Hexane, 1-methoxy- (*Methyl Hexyl Ether*)		Y	http://www.thegoodscentscompany.com/data/rw1017011.html#tosafty European information : Most important hazard(s): *Xi - Irritant* R 38 - Irritating to skin. *S 24/25 - Avoid contact with skin and eyes.*
Hexyl caproate (*Hexyl Hexanoate*)	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/6378-65-0 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rw1028161.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
Hydroxycitronellal	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7888#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H317 (100%): May cause an allergic skin reaction [Warning Sensitization, Skin]*

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			https://chem.nlm.nih.gov/chemidplus/rn/startswith/107-75-5 Skin/eye irritant https://cosmeticsinfo.org/ingredient/hydroxycitronellal-0 The Food and Drug Administration (FDA) has approved the use of Hydroxycitronellal as a flavoring agent for direct addition to food. The safety of Hydroxycitronellal has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Hydroxycitronellal in fragrances because of potential sensitization. More safety Information: Link to FDA Code of Federal Regulations for Hydroxycitronellal: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=hydroxycitronellal The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Hydroxycitronellal does not present a safety concern at current levels of intake when used as a flavoring agent. Link to the JECFA safety evaluation of Hydroxycitronellal: http://www.inchem.org/documents/jecfa/jeceval/jec_1076.htm The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Hydroxycitronellal and determined that it was Generally Recognized as Safe for use as a flavoring substance. In Europe, Hydroxycitronellal is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Hydroxycitronellal must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1000972.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *R 43 - May cause sensitisation by skin contact.* *S 24 - Avoid contact with skin.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317*
Isoamyl Acetate	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr469.pdf https://pubchem.ncbi.nlm.nih.gov/compound/31276#section=Safety-and-Hazards Signal: Danger GHS Hazard Statements *H315: Causes skin irritation [Warning Skin corrosion/irritation]* Health Hazard

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			VAPOR: Irritating to eyes, nose and throat. If inhaled, will cause nausea, headache or dizziness. LIQUID: Irritating to skin and eyes. Harmful if swallowed. (USCG, 1999) from CAMEO Chemicals https://cosmeticsinfo.org/ingredient/isoamyl-acetate The Food and Drug Administration reviewed the safety of Amyl Acetate and approved its use as an indirect food additive as a component of adhesives. FDA: Link to the Code of Federal Regulations for Amyl Acetate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=175.105&SearchTerm=amyl%20acetate The use of Amyl Acetate and Isoamyl Acetate are permitted in Europe subject to the general provisions of the Cosmetics Regulation of the European Union. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 The Joint FAO/WHO Expert Committee on Food Additives has established an Acceptable Daily Intake of 0-3 mg Isoamyl Acetate/kg body weight. No safety concern was indicated at current levels of intake when used as a flavoring agent. http://www.inchem.org/documents/jecfa/jeceval/jec_1138.htm http://www.thegoodscentscompany.com/data/rw1006712.html#tosafty European information : Most important hazard(s): Xi - Irritant *R 66 - Repeated exposure may cause skin dryness or cracking.*
Isopropyl Palmitate		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR623.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PRN475.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr238.pdf https://cosmeticsinfo.org/ingredient/isopropyl-palmitate https://chem.nlm.nih.gov/chemidplus/rn/startswith/142-91-6 Skin/eye irritant http://www.thegoodscentscompany.com/data/rw1019311.html#tosafty European information : Most important hazard(s): *S 24/25 - Avoid contact with skin and eyes.* https://pubchem.ncbi.nlm.nih.gov/compound/8907#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]* Skin, Eye, and Respiratory Irritations

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

<table>
<tr><th>Chemical</th><th>Baby Powder</th><th>Shower-to-Shower</th><th></th></tr>
<tr><td></td><td></td><td></td><td>Direct contact may cause mild irritation /of the/ eye. Prolonged or repeated contact /with the skin/ may cause mild irritation...
European Commission, ESIS; IUCLID Dataset,Isopropyl Palmitate (142-91-6) p.24 (2000 CD-ROM edition).
from HSDB

A human skin irritant.
Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 1991
from HSDB

NIOSH Toxicity Data
<table><tr><td>Measurement</td><td>System</td><td>Route/Organism</td><td>Dose</td><td>Effect</td><td>Date</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /human</td><td>84 mg/3D- intermittent</td><td>mild</td><td>January 1997</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>500 mg/24H</td><td>moderate</td><td>January 1997</td></tr></table></td></tr>
<tr><td>Juniperus Communis Fruit Oil</td><td>Y</td><td></td><td>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr328.pdf

https://www.ewg.org/guides/substances/10468-JUNIPERUSCOMMUNISFRUITOIL#.W31_sehKiUk
Component: D-LIMONENE
Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive

https://chem.nlm.nih.gov/chemidplus/number/startswith/8012-91-7
Skin/eye irritant

https://cosmeticsinfo.org/ingredient/juniperus-communis-fruit-extract
The Food and Drug Administration (FDA) includes Juniperus communis berry oil on its list of essential oils considered Generally Recognized As Safe (GRAS) as food for human consumption. Juniper tar is approved for use as an analgesic, anesthetic, and antipruretic active ingredient in Over-The-Counter (OTC) anorectal drug products.

Link to FDA Code of Federal Regulations for Juniper berry oil and Juniper Tar

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.20&SearchTerm=juniperus
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=346.16&SearchTerm=juniper%20tar

Juniper Extracts and Juniper Tar may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union.

Link to the EU Cosmetic Regulation:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013

http://www.thegoodscentscompany.com/data/es1029741.html
European information :
Most important hazard(s):
R 38 - Irritating to skin.</td></tr>
</table>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			R 43 - May cause sensitisation by skin contact. *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Lavandula Angustifolia (Lavender) Oil	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/8000-28-0 Skin/eye irritant https://www.ewg.org/guides/substances/3172-LAVANDULAANGUSTIFOLIALAVENDER#.W319L-hKiUk Component: LINALOOL Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive Component: LINALOOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Component: LINALYL ACETATE The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Component: GERANIOL Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive Component: GERANIOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41. Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Pia Forsström, Ann-Marie Wennberg, Ann-Therese Karlberg & Mihály Matura. 2009. Air oxidation increases skin irritation from fragrance terpenes. Contact dermatitis 60(1), 32-40. Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1. Component: LINALOOL This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8. http://www.thegoodscentscompany.com/data/es1007471.html#tosafty

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			European information : Most important hazard(s): *Xn - Harmful.* *R 36/38 - Irritating to skin and eyes.* *R 43 - May cause sensitisation by skin contact.* *S 24/25 - Avoid contact with skin and eyes.*
Lemon oil terpenes	Y		https://echa.europa.eu/substance-information/-/substanceinfo/100.108.674 Danger! According to the classification provided by companies to ECHA in CLP notifications this substance may be fatal if swallowed and enters airways, is very toxic to aquatic life with long lasting effects, is very toxic to aquatic life, is a flammable liquid and vapour, *causes skin irritation and may cause an allergic skin reaction.*
Levisticum Officinale Oil (*Levisticum Officinale Leaf Oil*)		Y	https://chem.nlm.nih.gov/chemidplus/rn/startswith/8016-31-7 *Skin/eye irritant*
Linalool	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/78-70-6 *Skin/eye irritant* https://www.ewg.org/guides/substances/3258-LINALOOL#.W312eOhKiUk Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41. This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Pia Forsström, Ann-Marie Wennberg, Ann-Therese Karlberg & Mihály Matura. 2009. Air oxidation increases skin irritation from fragrance terpenes. Contact dermatitis 60(1), 32-40. This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1. This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8. https://cosmeticsinfo.org/ingredient/linalool-0 The Food and Drug Administration (FDA) includes Linalool on its list of substances considered Generally Recognized As Safe (GRAS) as flavoring substance. The safety of Linalool has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. *The IFRA Standard restricts the use of Linalool in fragrances because of potential sensitization.* More safety Information: Link to FDA Code of Federal Regulations for Linalool: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=linalool

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Linalool does not present a safety concern at current levels of intake when used as a flavoring agent. Link to the JECFA safety evaluation of Linalool: http://www.inchem.org/documents/jecfa/jeceval/jec_1271.htm The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of linalool and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring substance. *In Europe, Linalool is included on the list of "allergenic" substances*. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Linalool must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1007872.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *R 43 - May cause sensitisation by skin contact.* *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* https://pubchem.ncbi.nlm.nih.gov/compound/6549#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (96.96%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (53.26%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Skin, Eye, and Respiratory Irritations *A skin irritant.* Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2232 from HSDB ... *Linalool must be regarded as a skin irritant and should be seen as mildly irritant for man*. ... Linalool is at most a moderate eye irritant; moreover, in about a third of human subjects it did not cause any eye irritation at 320 ppm. Organization for Economic Cooperation and Development; Screening Information Data Set for LINALOOL (78-70-6) p.14 (March 2002). from HSDB NIOSH Toxicity Data https://pubchem.ncbi.nlm.nih.gov/compound/6549#section=NIOSH-Toxicity-Data&fullscreen=true

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

<table>
<tr><th>Chemical</th><th>Baby Powder</th><th>Shower-to-Shower</th><th></th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th>Measurement</th><th>Date</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th></tr>
<tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>eye /rabbit</td><td>100 µL</td><td>moderate</td></tr>
<tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>eye /rabbit</td><td>0.1 mL/1H</td><td>moderate</td></tr>
<tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /guinea pig</td><td>100 mg/24H</td><td>moderate</td></tr>
<tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /human</td><td>32%/72H</td><td>mild</td></tr>
<tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /human</td><td>10%/2D</td><td></td></tr>
<tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /man</td><td>16 mg/48H</td><td>mild</td></tr>
<tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /rabbit</td><td>500 mg/24H</td><td>mild</td></tr>
<tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /rabbit</td><td>100 mg/24H</td><td>severe</td></tr>
</table>
</td></tr>
<tr><td>Linalyl Acetate</td><td>Y</td><td></td><td>
https://pubchem.ncbi.nlm.nih.gov/compound/8294#section=Safety-and-Hazards
Signal: Warning
GHS Hazard Statements

H315 (98.36%): Causes skin irritation [Warning Skin corrosion/irritation]

Skin, Eye, and Respiratory Irritations
A severe skin irritant.
Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2232
from HSDB

Linalyl acetate (100%) appeared to be severely irritating to rabbit skin and moderately irritating to the skin of the guinea pig. In a test with miniature swines, application of 0.05 g linalyl acetate under a patch for 48 hours /caused/ no irritation ... .
Organization for Economic Cooperation and Development; Screening Information Data Set for LINALYL ACETATE (115-95-7) p.11 (March 2002). Available from, as of July 14, 2008: http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html
from HSDB

https://chem.nlm.nih.gov/chemidplus/rn/startswith/115-95-7
Skin/eye irritant

https://www.ewg.org/guides/substances/3259-LINALYLACETATE#.W31y2-hKiUk
The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans.

Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive
</td></tr>
</table>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			http://www.thegoodscentscompany.com/data/rw1007892.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Mentha Arvensis Leaf Oil	Y		http://www.thegoodscentscompany.com/data/es1003041.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 37/38 - Irritating to respiratory system and skin.* https://www.ewg.org/guides/substances/6437-MENTHAARVENSISWILDMINTOIL#.W31vDuhKiUk Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41. Johanna Bråred Christensson, Pia Forsström, Ann-Marie Wennberg, Ann-Therese Karlberg & Mihály Matura. 2009. Air oxidation increases skin irritation from fragrance terpenes. Contact dermatitis 60(1), 32-40. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1. Component: LINALOOL This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8. The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Component: LINALOOL Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive Component: LINALOOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive
Menthyl Acetate	Y		http://www.thegoodscentscompany.com/data/rw1046271.html#tosafty European information : Most important hazard(s):

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			Xi - Irritant *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.*
Methyl Anthranilate	Y		https://pubchem.ncbi.nlm.nih.gov/compound/8635#section=GHS-Classification Health Hazard SYMPTOMS: *This compound is an irritant to the skin. ACUTE/CHRONIC HAZARDS: This compound may cause irritation on contact*. (NTP, 1992). from CAMEO Chemicals Skin, Eye, and Respiratory Irritations Prolonged inhalation may lead to respiratory tract irritation. ...*Prolonged or repeated /skin or eye/ contact may result in mechanical irritation*. Becker Underwood, Inc; Material Safey Data Sheet for Methyl Anthranilate 134-20-3 (Date Revised: February 23, 2000). Available from, as of November 11, 2003: http://www.beckerunderwood.com/msds/rejexit_ff.html from HSDB https://chem.nlm.nih.gov/chemidplus/rn/startswith/134-20-3 Skin/eye irriatant https://www.ewg.org/guides/substances/11032-METHYLANTHRANILATE#.W3yJwuhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows negative results for causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/rw1008211.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Methyl Benzoate	Y	Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr578.pdf https://cosmeticsinfo.org/ingredient/methyl-benzoate The Food and Drug Administration (FDA) permits Methyl Benzoate, Ethyl Benzoate, Propyl Benzoate, Isopropyl Benzoate and Isobutyl Benzoate to be used as flavoring agents for direct addition to food. Butyl Benzoate is permitted for use as an indirect food additive as a component of adhesives. Link to FDA Code of Federal Regulations https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=benzyl%20benzoate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=175.105

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			The European Union lists salts and esters of benzoic acid (including Methyl Benzoate, Ethyl Benzoate, Propyl Benzoate, Butyl Benzoate, Isopropyl Benzoate and Isobutyl Benzoate) as preservatives that may be safety used in cosmetics at concentrations up to 0.5% (See Annex IV). Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 http://www.thegoodscentscompany.com/data/rw1015012.html#tosafty European information : Most important hazard(s): Xn - Harmful. R 36/38 - Irritating to skin and eyes. R 42/43 - May cause sensitization by inhalation and skin contact. S 24/25 - Avoid contact with skin and eyes.
Methyl Cinnamate	Y		https://pubchem.ncbi.nlm.nih.gov/compound/637520#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H317 (100%): May cause an allergic skin reaction [Warning Sensitization, Skin]* https://www.ewg.org/guides/substances/18329-METHYLCINNAMATE#.W3yEyuhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/rw1417571.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes.
Methyl Salicylate	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr302.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/TR766.pdf https://chem.nlm.nih.gov/chemidplus/rn/startswith/119-36-8 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/4133#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (23.08%): Causes skin irritation [Warning Skin corrosion/irritation]* Health Hazard *Harmful if swallowed, inhaled, absorbed through skin*. Vapor mist is irritating to the eyes, mucous membranes, upper respiratory tract and skin. Ingestion of relatively small amount causes severe poisoning and death. Causes nausea, vomiting, acidosis, pulmonary edema, pneumonia, convulsions and death. (USCG, 1999) from CAMEO Chemicals Effects of Short Term Exposure *The substance is irritating to the eyes and skin*. The substance may cause effects on the central nervous system. This may result in shock and death. The effects may be delayed. Medical observation is indicated.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			from ILO-ICSC http://www.thegoodscentscompany.com/data/rw1008472.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.* https://www.ewg.org/guides/substances/3576-METHYLSALICYLATE#.W3yBzuhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive https://cosmeticsinfo.org/ingredient/methyl-salicylate The Food and Drug Administration (FDA) has reviewed the safety of Salicylic Acid and Methyl Salicylate and permits their use as indirect food additives. Salicylic Acid is approved for use in Over-the-Counter (OTC) drug products. Salicylic acid is widely used as an FDA approved safe and effective acne drug product. It is also approved for use in OTC drugs for corn, callusand wart removal, as well as in antidandruff OTC drug products. Ethylhexyl Salicylate and TEA-Salicylate are permitted by FDA for use as active ingredients in OTC sunscreen drug products. Ethylhexyl Salicylate may be used at concentrations up to 5%, and TEA-Salicylate may be used at concentrations up to 12%. Link to the FDA Code of Federal Regulations for Salicylic Acid, Sodium Salicylate, Methyl Salicylate, and Octyl (Ethylhexyl) Salicylate Acne Active Ingredients Adhesives Sunscreen Active Ingredients Wart Remover Active Ingredients Corn and Callus Remover Active ingredients Control of Dandruff Salicylic Acid it salts are listed in the Cosmetics Directive of the European Union and may be used as preservatives in cosmetics and personal care products at a maximum concentration of 0.5% (see Annex VI). In Europe, for uses other than as a preservative, Salicylic Acid may be used in rinse-off hair products at concentrations up to 3%, and in other products at concentrations up to 2% (see Annex III). Salicylic Acid should not to be used in products for children under 3 years of age, except for shampoo formulations. Ethylhexyl Salicylate is listed in the Cosmetics Directive of the European Union and may be used as a UV filter at a concentration up to 5% (see Annex VII). Health Canada permits the use of Salicylic Acid in cosmetics and personal care products in concentrations equal to or less than 2%. Ethylhexyl Salicylate (up to 6%) and TEA-Salicylate (up to 12%) are permitted for use in sunscreen products in Canada.
Myristica Fragrans (Nutmeg) Kernel Oil (*Nutmeg oil*)	Y	Y	https://pubchem.ncbi.nlm.nih.gov/compound/6850746#section=Canonical-SMILES https://chem.nlm.nih.gov/chemidplus/rn/startswith/8008-45-5 *Skin/eye irritant* https://www.ewg.org/guides/substances/3802-MYRISTICAFRAGRANSNUTMEGKERNELOIL#.W3x8BuhKiUk Component: D-LIMONENE Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive Impurity: FORMALDEHYDE

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			Causes skin irritation. NIOSH Pocket Guide to Chemical Hazards - Centers for Disease Control and Prevention (CDC)
Myroxylon Balsamum (Balsam Tolu) Resin	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/9000-64-0 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/rs1011391.html European information : Most important hazard(s): Xi - Irritant *R 43 - May cause sensitisation by skin contact.*
Myroxylon Pereirae (Balsam Peru) Oil	Y		https://www.ewg.org/skindeep/ingredient/720874/MYROXYLON_PEREIRAE_(BALSAM_PERU)_OIL/#.W3x4b-hKiUk http://www.thegoodscentscompany.com/data/es1009811.html#tosafty European information : Most important hazard(s): Xi - Irritant *R 38 - Irritating to skin.* *R 43 - May cause sensitisation by skin contact.* *S 24/25 - Avoid contact with skin and eyes.* *S 28 - After contact with skin, wash immediately with plenty of water.*
Nonan-1-ol (*Nonyl Alcohol*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/8914#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements *H315 (17.45%): Causes skin irritation [Warning Skin corrosion/irritation]*
Octan-2-one (*2-Octanone*)		Y	https://pubchem.ncbi.nlm.nih.gov/compound/8093#section=Hazards-Identification Skin, Eye, and Respiratory Irritations 2-Octanone has a relatively low toxicity. *Direct skin contact may cause defatting and irritation of the skin.* Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. 6:301. from HSDB http://www.thegoodscentscompany.com/data/rw1001751.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 21 - Harmful in contact with skin.* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* *S 24/25 - Avoid contact with skin and eyes.*
Opoponax (*sweet myrrh*)	Y		https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_025b.pdf According to the results of these tests, summarized in the table, five of the tested samples (2 extracts and 3 oils) gave some positive results indicating that Opoponax products may have a *mild sensitizing potential depending on the origin and the quality of the product.* In the introductory report (ref. 29) it is stated that the earlier studies with positive resu1ts were most likely due to the utilization of samples that contained undefined impurities. The more recent studies yielding negative results used better-defined materials. However, in the same report it is also stated that the source of the samples with positive results is unknown, and may have been obtained from Pastinaca opopanax L. (Fam: Umbelliferare) instead of from genuine opoponax gums from Commiphora erythraea var. glabrescens Engler (Fam: Burseracae). Taking also into consideration that the most recent studies mentioned above were carried out in 1979-1980, these two partially contradicting statements cannot be evaluated.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
p-Cresol	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr277.pdf https://cosmeticsinfo.org/ingredient/p-cresol The Food and Drug Administration (FDA) permits the use of Thymol as a direct and food additive (as a flavoring substance) and as an indirect food additive (for use in paper an paperboard in contact with food). Link to FDA Code of Federal Regulations for Thymol https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=thymol https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=176.180&SearchTerm=thymol In the European Union, p-Chloro-m-Cresol, Sodium p-Chloro-m-Cresol at concentrations up to 0.2% and o-Cymen-5-ol (4-Isopropyl-m-cresol) at concentrations up to 0.1% are allowed to be used as preservatives (see Annex VI). Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 https://chem.nlm.nih.gov/chemidplus/rn/106-44-5 *Skin/eye irritant* Tumor Data http://www.thegoodscentscompany.com/data/rw1003851.html#tosafty European information : Most important hazard(s): T - Toxic. *R 24/25 - Toxic in contact with skin and if swallowed.* R 34 - Causes burns. *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Acute toxicity, Dermal (Category 3), H311* *Skin corrosion (Category 1B), H314* https://pubchem.ncbi.nlm.nih.gov/compound/2879#section=Hazards-Identification Signal: Danger GHS Hazard Statements *H311: Toxic in contact with skin [Danger Acute toxicity, dermal]* *H314: Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]* H351: Suspected of causing cancer [Warning Carcinogenicity] Health Hazard *SKIN: Intense burning, loss of feeling, white discoloration and softening.* Gangrene may occur. (USCG, 1999) from CAMEO Chemicals Skin, Eye, and Respiratory Irritations

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			... Causes severe eye and skin burns. ... Irritating to skin, eyes, and respiratory system. Symptoms include severe irritation of eyes with tearing, conjunctivitis, and corneal edema. *May act as a skin sensitizer*. National Fire Protection Association; Fire Protection Guide to Hazardous Materials. 14TH Edition, Quincy, MA 2010, p. 49-48 from HSDB NIOSH Toxicity Data Tumorigenic Data | June 2017 | skin/mouse | lowest published toxic dose: 2280 mg/kg/20W-intermittent | Tumorigenic: Neoplastic by RTECS criteria Skin and Appendages: Tumors
p-Cymene	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7463#section=Hazards-Identification *p-Cymene is reported to be a primary skin irritant ... .* Monograph on Fragrance Raw Materials: p-Cymene; Food and Cosmetics Toxicology 12 (3): 401-2 (1974) from HSDB http://www.thegoodscentscompany.com/data/rw1032712.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 36/37/38 - Irritating to eyes, respiratory system, and skin..* *S 24/25 - Avoid contact with skin and eyes..* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
Pelargonium Graveolens Flower Oil *(Geranium*)	Y		https://www.ewg.org/guides/substances/4320-PELARGONIUMGRAVEOLENSGERANIUMEXTRACT#.W3xhjehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established *contact allergen* in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Directive Component: GERANIOL Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive Component: GERANIOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Component: LINALOOL Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive. Component: LINALOOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1. Component: LINALOOL This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8. https://pubchem.ncbi.nlm.nih.gov/compound/637566#section=GHS-Classification (Geraniol): Signal: Danger GHS Hazard Statements *H315 (98.89%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (99.59%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Skin, Eye, and Respiratory Irritations *A severe human skin irritant.* Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 1440. from HSDB
Pentadecalactone (*omega-pentadecalactone*) (*Oxacyclohexadecan-2-one*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/235414#section=GHS-Classification Signal: Warning GHS Hazard Statements *H317 (18.4%): May cause an allergic skin reaction [Warning Sensitization, Skin]* http://www.thegoodscentscompany.com/data/rw1004211.html#tosafty European information : Most important hazard(s): *S 24/25 - Avoid contact with skin and eyes.*
Petitgrain oil, Paraguay (*Citrus aurantium fruit oil*)	Y		https://echa.europa.eu/substance-information/-/substanceinfo/100.252.174 Essential oil of Petitgrain obtained from the leaves and twigs of Citrus aurantium (Rutaceae) by distillation Danger! According to the classification provided by companies to ECHA in REACH registrations this substance may be fatal if swallowed and enters airways, is toxic to aquatic life with long lasting effects, causes serious eye irritation and *causes skin irritation.*
Phenethyl Acetate	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7654#section=Hazards-Identification Signal: Danger GHS Hazard Statements http://www.thegoodscentscompany.com/data/rw1010032.html#tosafty European information : Most important hazard(s): *S 24/25 - Avoid contact with skin and eyes.*
Phenethyl Alcohol	Y	Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr134.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/prn547.PDF

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			http://www.thegoodscentscompany.com/data/rw1010052.html#tosafty European information : Most important hazard(s): Xn - Harmful. *R 21/22 - Harmful in contact with skin and if swallowed.* *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.* https://cosmeticsinfo.org/ingredient/phenethyl-alcohol-0 More safety Information: Link to FDA Code of Federal Regulations for Phenethyl Alcohol https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=phenethyl%20alcoho Phenethyl Alcohol may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 https://www.ewg.org/guides/substances/4400-PHENETHYLALCOHOL#.W3xBDehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing *contact allergy in humans*. Opinion on Fragrance allergens in cosmetics (2011) – EU Cosmetics Directive https://pubchem.ncbi.nlm.nih.gov/compound/6054#section=GHS-Classification Signal: Warning Effects of Short Term Exposure *The substance is irritating to the eyes, skin and respiratory tract*. The substance may cause effects on the central nervous system. If swallowed the substance may cause vomiting and could result in aspiration pneumonitis. from ILO-ICSC* Effects of Long Term Exposure Animal tests show that this substance possibly causes toxicity to human reproduction or development. from ILO-ICSC* Skin Symptoms Redness. from ILO-ICSC* ** The International Chemical Safety Cards (ICSC) are data sheets intended to provide essential safety and health information on chemicals in a clear and concise way. The primary aim of the cards is to promote the safe use of chemicals in the workplace.* https://pubchem.ncbi.nlm.nih.gov/compound/6054#section=Toxicity From NIOSH Skin and Eye Irritation | | eye /rabbit | 12 gm/10M | mild | July 2016

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			Skin and Eye Irritation | eye /rabbit | 750 µg/24H | severe | July 2016 Skin and Eye Irritation | skin /guinea pig | 100% | mild | July 2016 Skin and Eye Irritation | skin /guinea pig | 100 mg/24H | moderate | July 2016 Skin and Eye Irritation | skin /rabbit | 100 mg/24H | moderate | July 2016
Phenethyl Benzoate	Y		http://www.thegoodscentscompany.com/data/rw1012671.html#tosafty European information : Most important hazard(s): Xi - Irritant *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.*
Phenoxyethanol	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr139.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR609.pdf https://cosmeticsinfo.org/ingredient/phenoxyethanol-0 European Union (E.U.) Regulation (EC) No. 1223/2009 of the European Union lists phenoxyethanol in Annex V, the list of preservatives allowed in cosmetic products. The maximum concentration in ready for use concentrations is 1.0%. https://chem.nlm.nih.gov/chemidplus/rn/122-99-6 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/31236#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (75.94%): Causes skin irritation [Warning Skin corrosion/irritation]* *A skin and severe eye irritant.* Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2904 from HSDB
phenylacetaldehyde	Y		https://www.ewg.org/guides/substances/16215-PHENYLACETALDEHYDE#.W3w8T-hKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing contact allergy in humans Opinion on Fragrance allergens in cosmetics (2011) EU Cosmetics Directive https://pubchem.ncbi.nlm.nih.gov/compound/998#section=GHS-Classification Signal: Danger

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			GHS Hazard Statements *H314 (74.67%): Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]* *H317 (96.46%): May cause an allergic skin reaction [Warning Sensitization, Skin]* http://www.thegoodscentscompany.com/data/rw1009931.html#tosafty European information : Most important hazard(s): Xn - Harmful *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* *R 43 - May cause sensitisation by skin contact.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315*
p-Methyl Acetophenone	Y		https://chem.nlm.nih.gov/chemidplus/rn/122-00-9 *Skin/eye irritant* https://pubchem.ncbi.nlm.nih.gov/compound/8500#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (79.94%): Causes skin irritation [Warning Skin corrosion/irritation]* http://www.thegoodscentscompany.com/data/rw1008191.html#tosafty European information : Most important hazard(s): Xn - Harmful. R 22 - Harmful if swallowd. *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.*
Pogostemon Cablin Oil (Patchouli)	Y	Y	https://chem.nlm.nih.gov/chemidplus/rn/8014-09-3 *Skin/eye irritant* http://www.thegoodscentscompany.com/data/es1031631.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* *S 24/25 - Avoid contact with skin and eyes.* Signal word Warning Hazard statement(s) *H316 - Causes mild skin irritation*
Propanedioic acid, diethyl ester (*Diethyl Malonate*)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7761#section=Toxicity

Measurement	System	Route/Organism	Dose	Effect	Date
Skin and Eye Irritation		*skin /rabbit*	*500 mg/24H*	*mild*	*January 1997*

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
Propanoic acid, phenylmethyl ester (*Benzyl Propionate*)	Y	Y	http://www.thegoodscentscompany.com/data/rw1001772.html#tosafty European information : Most important hazard(s): *S 24/25 - Avoid contact with skin and eyes.* Signal word Warning
Propylene Glycol		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR560.PDF https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr77.pdf https://cosmeticsinfo.org/ingredient/propylene-glycol Safety Information: United States FDA: The agency includes propylene glycol on its list of substances considered Generally Recognized As Safe (GRAS) for direct addition to food. Polypropylene glycol is also permitted as an indirect food additive for use as a de-foaming agent. NTP: In 2003, the National Toxicology Program's (NTP) Center for the Evaluation of Risk to Human Reproduction (CERHR) Expert Panel reviewed the reproductive and developmental effects potential of propylene glycol and concluded that there is "negligible concern for reproductive or developmental toxicity to humans." European Union (EU) Propylene glycol and PPGs may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union. https://www.ewg.org/guides/substances/4889-PROPYLENEGLYCOL#.W3wnlehKiUk The OECD concluded that *Propylene Glycol does not cause sensitization by skin contact*. Organisation for Economic Co-Operation and Development. 2001. Propylene glycol CAS No. 57-55-6. SIDS Initial Assessment Report for 11th SIAM. The OECD concluded that *Propylene Glycol is not a skin irritant*. Organisation for Economic Co-Operation and Development. 2001. Propylene glycol CAS No. 57-55-6. SIDS Initial Assessment Report for 11th SIAM. The Agency for Toxic Substances and Disease Registry concluded that *Propylene Glycol has marginal irritant properties*. U.S. Department of Health and Human Services - Agency for Toxic Substances and Disease Registry. 1997. Toxicological Profile For Propylene Glycol. The Agency for Toxic Substances and Disease Registry found cases of sensitivity recorded in the *Propylene Glycol literature and concluded that it might be a sensitizer.* U.S. Department of Health and Human Services - Agency for Toxic Substances and Disease Registry. 1997. Toxicological Profile For Propylene Glycol. https://pubchem.ncbi.nlm.nih.gov/compound/1030#section=NIOSH-Toxicity-Data&fullscreen=true

Skin and Eye Irritation	June 2017		eye /rabbit	100 mg	mild
Skin and Eye Irritation	June 2017		eye /rabbit	500 mg/24H	mild

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			Skin and Eye Irritation | June 2017 | | skin /child | 30%/96H-continuous | moderate Skin and Eye Irritation | June 2017 | | skin /human | 500 mg/7D | mild Skin and Eye Irritation | June 2017 | | skin /human | 104 mg/3D- intermittent | moderate Skin and Eye Irritation | June 2017 | | skin /human | 20% Skin and Eye Irritation | June 2017 | | skin /man | 10%/2D Skin and Eye Irritation | June 2017 | | skin /woman | 30%/96H open irritation test | mild Mutation Data | June 2017 | Cytogenetic Analysis | subcutaneous/mouse | 8000 mg/kg Mutation Data | June 2017 | Cytogenetic Analysis | fibroblast/hamster | 32 gm/L
Santalum Album (Sandalwood) Oil	Y		http://www.thegoodscentscompany.com/data/es1010871.html#tosafty European information : Most important hazard(s): *Xi - Irritant* R 36/38 - Irritating to skin and eyes. R 43 - May cause sensitisation by skin contact. *S 24/25 - Avoid contact with skin and eyes.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317* https://www.ewg.org/guides/substances/5309-SANTALUMALBUMSANDALWOODOIL#.W3wkbehKiUk Some concern for skin allergies & irritation
Tartaric Acid (*laevo-(+)-tartaric acid*)	Y		http://www.thegoodscentscompany.com/data/rw1034811.html European information : Most important hazard(s): *Xi - Irritant* *R 36/37/38 - Irritating to eyes, respiratory system, and skin.* *S 24/25 - Avoid contact with skin and eyes.* https://cosmeticsinfo.org/ingredient/tartaric-acid Safety Information: The Food and Drug Administration (FDA) has reviewed the safety of Potassium Sodium Tartrate and has affirmed its status as Generally Recognized as Safe (GRAS) as a direct food substance. FDA has approved the use of Tartaric Acid and Potassium Sodium Tartrate in Over-the-Counter (OTC) antacid drug products.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			More safety Information: Tartaric acid is metabolically inert in the human body. Link to FDA Code of Federal Regulations for Tartaric Acid https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1099&SearchTerm=tartaric%20acid https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=331.11&SearchTerm=tartaric%20acid Link to FDA Code of Federal Regulations for Potassium Sodium Tartrate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1804&SearchTerm=sodium%20potassium%20tartrate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=331.11&SearchTerm=sodium%20potassium%20tartrate Tartaric Acid and its salts may be used in cosmetics and personal care products marketed in the Europe according to the https://cosmeticsinfo.org/glossary/letter_g#General_Provisions_of_the_Cosmetics_Regulation_of_the_European_Union Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013
TBHQ (*t-Butylhydroquinone*)		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr118.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR609.pdf https://pubchem.ncbi.nlm.nih.gov/compound/16043#section=GHS-Classification Signal: Warning GHS Hazard Statements *H312 (27.89%): Harmful in contact with skin [Warning Acute toxicity, dermal]* *H315 (20.64%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (32.21%): May cause an allergic skin reaction [Warning Sensitization, Skin]* Health Hazard SYMPTOMS: *Symptoms of exposure to this compound include irritation of the skin and eyes and dermatitis*. (NTP, 1992) https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+838 Clinical Effects: 0.2.1 SUMMARY OF EXPOSURE 0.2.1.1 ACUTE EXPOSURE … D) WITH THERAPEUTIC USE 1) DERMAL: Localized contact dermatitis, pruritus, dry skin, burning, desquamation, erythema, brown or orange-brown nail discoloration, paradoxical ochronosis-like hyperpigmentation of the skin, and hypersensitivity reactions.
Terpineol	Y	Y	https://pubchem.ncbi.nlm.nih.gov/compound/17100#section=GHS-Classification Signal: Warning GHS Hazard Statements H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			HUMAN EXPOSURE AND TOXICITY: In human subjects, alpha-terpineol had a low irritative potency but a strong odor. *Two dermatitis patients were reported to be sensitized to alpha-terpineol, although attempts to induce skin sensitization in volunteers using a dilute solution of alpha-terpineol were unsuccessful.* ANIMAL STUDIES*: In rabbits neat alpha-terpineol was a moderate skin irritant.* http://www.thegoodscentscompany.com/data/rw1011252.html#tosafty European information : Most important hazard(s): *Xi - Irritant* *R 36/38 - Irritating to skin and eyes.* S 24/25 - Avoid contact with skin and eyes. Hazards identification *Skin irritation (Category 2), H315*
Trichloromethyl Phenyl Carbinyl Acetate (*Rosacetol*)		Y	http://www.thegoodscentscompany.com/data/rw1002671.html#tosafty European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. S 24/25 - Avoid contact with skin and eyes.
Undecylenal *Undec-10-enal* *10-undecenal (aldehyde C-11 undecylenic)*	Y		https://www.ewg.org/guides/substances/15138-UNDECYLENAL#.W3sGQehKiUk This substance is Generally Recognized as Safe (GRAS) as a food additive by the US Food and Drug Administration *Only in: Household Cleaners* low Concer FDA - Priority based Assessment of Food Additive (PAFA) - U.S. Food and Drug Administration (FDA) http://www.thegoodscentscompany.com/data/rw1000332.html#tosafty Most important hazard(s): N - Dangerous for the environment. *R 36/38 - Irritating to skin and eyes.* *R 43 - May cause sensitisation by skin contact.* GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Acute toxicity, dermal (Category 5), H313 *Skin irritation (Category 2), H315* *Skin sensitisation (Category 1), H317* Signal word Warning Hazard statement(s) H313 - May be harmful in contact with skin H315 - Causes skin irritation H317 - May cause an allergic skin reaction https://pubchem.ncbi.nlm.nih.gov/compound/8187#section=GHS-Classification Signal: Warning GHS Hazard Statements *H315 (99.9%): Causes skin irritation [Warning Skin corrosion/irritation]* *H317 (91%): May cause an allergic skin reaction [Warning Sensitization, Skin]*

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			EPA Safer Chemical 10-Undecenal - Yellow triangle - The chemical has met Safer Choice Criteria for its functional ingredient-class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. (See Safer Choice Criteria). While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.
Vanillin	Y		http://www.thegoodscentscompany.com/data/rw1011712.html#tosafty https://chem.nlm.nih.gov/chemidplus/name/vanillin
Vetiveria Zizanoides Root Oil	Y		https://www.ewg.org/skindeep/ingredient/724810/VETIVERIA_ZIZANOIDES_ROOT_OIL/#.W3sAhuhKiUk Multiple, additive exposure sources *Irritation (skin, eyes, or lungs)* One or more animal studies show skin irritation at low doses RTECS®- Food and Cosmetics Toxicology Organ system toxicity (non-reproductive) Classified as not expected to be potentially toxic or harmful Environment Canada Domestic Substance List http://www.thegoodscentscompany.com/data/es1695591.html#tosafty Most important hazard(s): Xi - Irritant R 38 - Irritating to skin.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
1-Phenylethyl acetate (*Methylphenylcarbinyl acetate*)	Y		http://www.thegoodscentscompany.com/data/rw1011092.html **European information :** **Most important hazard(s):** S 24/25 - Avoid contact with skin and eyes. **Signal word Warning**
3,7-Dimethylnona-2,6-dienentrile (*3,7-Dimethylnona-2,6-dienenitrile* *Homogeranyl nitrile* *Lemonile* (Givaudan))		Y	http://www.thegoodscentscompany.com/data/rw1042831.html#tosafty **European information :** **Most important hazard(s):** S 24/25 - Avoid contact with skin and eyes.
3, 7-Dimethylocta-2,6-dien-1-yl phenylacetate (*geranyl phenyl acetate*)	Y		**Trans-3,7-Dimethyl-2,6-octadien-1-yl phenylacetate or Geranyl phenylacetate ???**
4-(2,5,6,6-Tetramethylcyclohex-2-en-1-yl)but-3-en-2-one *(4-(2,5,6,6-Tetramethyl-2-cyclo-hexen-1-yl)-3-buten-2-one* *Methyl-alpha-ionone*)	Y		http://www.thegoodscentscompany.com/data/rw1006691.html#tosafty **European information :** **Most important hazard(s):** None - None found. S 24 - Avoid contact with skin.
Acetic acid, anhydride, reaction products with 1,5,10-trimethyl-1,5,9-cyclododecatriene		Y	https://pubchem.ncbi.nlm.nih.gov/compound/53422908#section=Safety-and-Hazards **Signal: Warning** **GHS Hazard Statements** H317 (97.13%): May cause an allergic skin reaction [Warning Sensitization, Skin] https://echa.europa.eu/substance-information/-/substanceinfo/100.105.384 Warning! According to the classification provided by companies to ECHA in REACH registrations this substance is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction.
Aloe Barbadensis Leaf Extract		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr274.pdf http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2017/04/WC500225527.pdf
Amyris Balsamifera Bark Oil		Y	No Data

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
(*West Indian sandalwood oil*)			
Anthemis Nobilis Flower		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR653.pdf (Anthemis Nobilis Flower Extract, oil, water) Int J Toxicol. 2017 May/Jun;36(1_suppl):57S-66S. doi: 10.1177/1091581817705620. Safety Assessment of Anthemis nobilis-Derived Ingredients as Used in Cosmetics. Johnson W Jr, Heldreth B, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, Andersen FA. Abstract Anthemis nobilis (Roman chamomile) flower extract, anthemis nobilis flower oil, anthemis nobilis flower powder, and anthemis nobilis flower water are ingredients that function as fragrance ingredients and skin-conditioning agents in cosmetic products. These ingredients are being used at concentrations up to 10% (anthemis nobilis flower water) in cosmetic products. The available data indicate that these 4 ingredients are not irritating or sensitizing. Chemical composition data and the low use concentrations suggest that systemic toxicity would not be likely if percutaneous absorption of constituents were to occur. Formulations may contain more than 1 botanical ingredient; each may contribute to the final concentration of a single component. Manufacturers were cautioned to avoid reaching levels of plant constituents that may cause sensitization or other adverse effects. Industry should continue to use good manufacturing practices to limit impurities in the ingredient before blending into cosmetic formulations. The Expert Panel concluded that these ingredients are safe in the present practices of use and concentration in cosmetics, when formulated to be nonsensitizing.
Benzene, 1,2-dimethoxy- (*Veratrole* *1,2-dimethoxybenzene* *ortho-dimethyl hydroquinone*)	Y		No Data
Benzeneacetic acid, phenylmethyl ester (*Benzyl Phenylacetate*)	Y		No Data
Bulnesia sarmienti, ext. (*Bulnesia sarmientoi , verawood, Guaiol*)	Y		No Data
Caprylyl Alcohol	Y		Capryl alcohol or Caprylic alcohol????
Castoreum	Y		No Data
Celery seed (Apium graveolens L.)	Y		No Data
Chamomilla Recutita (Matricaria) Flower Oil	Y		https://www.cir-safety.org/sites/default/files/chamom032016tent.pdf
Citrus Aurantium Bergamia (Bergamot) Fruit Oil	Y		
Citrus Aurantium Dulcis (Orange) Peel Oil	Y		

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
Citrus Medica Limonum (Lemon) Peel Oil	Y		
Citrus Nobilis (Mandarin Orange) Peel Oil	Y		
Copper Chlorophyll	Y		https://cosmeticsinfo.org/ingredient/chlorophyllin-copper-complex-0 The Food and Drug Administration (FDA) has approved Chlorophyllin-Copper Complex as a color additive exempt from certification. As a color, Chlorophyllin-Copper Complex may be safely used for coloring dentifrices when it conforms to FDA specifications. FDA has also permits the use of Chlorophyllin-Copper Complex in Over-the-Counter (OTC) internal deodorant drug products. Internal deodorant drug products are taken internally to reduce odors from conditions such as colostomies, ileostomies or fecal incontinence. More safety Information: All color additives used in foods, drugs and cosmetics in the United States must be approved by FDA and listed in the Code of Federal Regulations. In some cases, FDA requires that each batch of color produced for use in regulated products can be used only if it is certified by the agency to meet strict specifications. FDA maintains a laboratory especially for this purpose and color manufacturers must pay a fee to support this activity. FDA only approves colors after extensive review of all safety data and publication of the basis for its approval in the Federal Register. Link to FDA Code of Federal Regulations for Chlorophyllin Copper Complex https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=357.810&SearchTerm=chlorophyllin-copper https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=73.2125&SearchTerm=chlorophyllin-copper Chlorophyllin-Copper Complex is listed as CI 75810 in the Cosmetics Directive of the European Union and may be used as a coloring agent in all cosmetics and personal care products (see Annex IV). When used in cosmetic products in the European Union, this ingredient must be called CI 75810. Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013 You can learn more about the regulation and labeling of colors at: https://www.personalcarecouncil.org/colors-cosmetics-regulation-and-nomenclature-united-states
Evernia Prunastri (Oakmoss) Extract (*evernia prunastri lichen extract*)	Y		No Data
Hex-3-en-1-yl acetate (*3-Hexenyl acetate, (3E)-)*	Y		http://www.thegoodscentscompany.com/data/rw1130931.html#tosafty **European information :** **Most important hazard(s):** S 24/25 - Avoid contact with skin and eyes.
Methyl 2-(methylamino)benzoate (*Methyl N,N-dimethylanthranilate*)	Y		No data
Methyl Hydrogenated Rosinate	Y	Y	No data

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	**Baby Powder**	**Shower-to-Shower**	
Musk Ketone		Y	https://echa.europa.eu/documents/10162/e6a84904-118b-447a-8766-f7bda48f7ce0 https://pubchem.ncbi.nlm.nih.gov/compound/6669#section=Safety-and-Hazards **Signal: Warning** **GHS Hazard Statements** ***H351 (99.74%): Suspected of causing cancer [Warning Carcinogenicity]***
Nonyl Acetate	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr469.pdf https://pubchem.ncbi.nlm.nih.gov/compound/8918#section=Safety-and-Hazards http://www.thegoodscentscompany.com/data/rw1015611.html#tosafty **European information :** **Most important hazard(s):** ***S 24/25 - Avoid contact with skin and eyes***.
Oils, styrax	Y		No data
Orris concrete (Iris pallida) (*orris rhizome concrete butter (iris pallida)*)	Y		http://www.thegoodscentscompany.com/search3.php?qName=orris+rhizome+concrete+butter+%28iris+pallida%29&submit.x=0&submit.y=0 **European information :** **Most important hazard(s):** ***S 24/25 - Avoid contact with skin and eyes.***
Indisan (Sandela) reaction product (*Sandela*)		Y	Sandela
Tanacetum vulgare, ext.	Y		No data
Thymus Vulgaris (Thyme) Oil	Y		
Tromethamine		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR630.pdf
Undecan-2-one	Y		http://www.thegoodscentscompany.com/data/rw1021151.html#tosafty **European information :** **Most important hazard(s):** S 24/25 - Avoid contact with skin and eyes.
1,5-Dimethyl-1-vinylhex-4-en-1-yl benzoate	Y		https://pubchem.ncbi.nlm.nih.gov/compound/Linalyl_benzoate#section=Cellular-Locations http://www.thegoodscentscompany.com/data/rw1030541.html

APPENDIX E

Photographs of Body Powder Products and Their Warnings


mildness
Johnson's
baby
powder
talco para bebés
keeps skin comfortable, dry & feeling soft all day
no parabens, phthalates or dyes
Johnson & Johnson
22 OZ (623g)
30039151


For over 125 years JOHNSON'S® formulas have been specially designed for baby's unique and delicate skin. Great for kids and adults too!
Hypoallergenic & tested with dermatologists
TO USE:
1. Shake powder directly into your hand, away from the face, before smoothing onto the skin.
2. Close tightly after use, store in a cool, dry place.
PARA USAR:
1. Antes de aplicarlo sobre la piel, agitar el polvo directamente en la mano, lejos de la cara.
2. Cerrar bien después de usar, y guardar en un lugar fresco y seco.
Every JOHNSON'S® product is designed to meet or exceed the top internationally recognized regulatory standards. Learn more at www.johnsonsbaby.com.
INGREDIENTS: Talc*, Fragrance
*naturally-derived ingredients
WARNING: Keep powder away from child's face to avoid inhalation, which can cause breathing problems. Avoid contact with eyes. For external use only. Close tightly after use. Keep out of reach of children. Do not use if quality seal is broken.
ADVERTENCIA: Mantener el talco alejado de la cara del niño para evitar la inhalación, que podría causar problemas respiratorios. Evitar el contacto con los ojos. Para uso externo exclusivamente. Cerrar bien después de usar. Mantener fuera del alcance de los niños. No usar si el sello de seguridad está roto.
Questions? 866-JNJ-BABY;
Outside US, dial collect 215-273-8755.
¿Preguntas? 866-JNJ-BABY;
Fuera de los EE. UU., llamada de cobro revertido al 215-273-8755.
Distributed by:/Distribuido por:
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Skillman, NJ 08558
© J&JCI 2018
Talc Made in China
Talco hecho en China
Care To Recycle™ our babies will inherit our planet®
30039152
3 81370 03014 0


Angel of mine™
Baby Powder
• Fresh, Clean & Soft
NET WT. 14 OZ (397 g)


LOT#19009W
Angel of mine™
ANGEL OF MINE™ Baby Powder is especially formulated to soothe and give a fresh, clean and fragrant feeling to your baby's delicate skin. Made of the finest talc, it helps to absorb excess moisture, keeping the baby's skin dry and soft for ultimate comfort.
Directions: After changing diapers and after every bath, dry baby's skin thoroughly and apply liberally as needed.
Ingredients: Talc and Fragrance.
Warnings: • Keep out of reach of children. • For external use only. • Avoid contact with eyes, discontinue use if irritation persists. • Avoid ingestion or accidental inhalation by baby.
This product contains talcum powder and is intended for external use only. Frequent application of talcum powder in the female genital area may increase the risk of ovarian cancer.
Seek professional assistance if needed.
This product is sold by weight, not volume. Settling will occur during handling & shipping.
7 81072 01021 9
983408 DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320
MADE IN U.S.A.


18101 072
ASSURED
Shower & Bath
Absorbent Body Powder
with Lavender
Compare to Shower to Shower®
NET WT 13oz (368 g)
ASSURED
Assured's Shower & Bath Absorbent Body Powder is specially made with cornstarch for greater absorbancy and baking soda to help neutralize odor. This Shower & Bath product is uniquely formulated to help you feel cool and confident all day.
CAUTION: Discontinue use if rash or irritation develops. Do not apply to broken or irritated skin.
WARNING: This product contains talcum powder and is intended for external use only. Frequent application of talcum powder in the female genital area may increase the risk of ovarian cancer.
KEEP OUT OF REACH OF CHILDREN
INGREDIENTS: Talc, Cornstarch, Sodium Bicarbonate, Fragrance, Tricalcium Phosphate, Polysaccharides, Aloe Barbadensis Extract, Chamomile (Anthemis Nobilis) Extract.
*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Shower to Shower®
DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
CHESAPEAKE, VA. 23320
PRODUCT OF USA
6 39277 17468 0


Spring Fresh®
Poudre Powder Talco
Tranquil Breeze
Brise fraîche
Brisa fresca
NET WT 5.0 OZ
140 g


INGREDIENTS: TALC, FRAGRANCE (PARFUM), BENZYL BENZOATE, BENZYL CINNAMATE, BENZYL SALICYLATE, CITRONELLOL, EUGENOL, ALPHA-ISOMETHYL IONONE, HEXYL CINNAMAL, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE, HYDROXYCITRONELLAL, BUTYLPHENYL METHYLPROPIONAL, LIMONENE, LINALOOL.
INGREDIENTES: TALCO, FRAGANCIA, BENZOATO DE BENCILO, CINAMATO DE BENCILO, SALICILATO DE BENCILO, CITRONELOL, EUGENOL, ALFA-ISOMETIL IONONE, HEXIL CINNAMAL, HIDROXI-ISOHEXIL 3-CICLOHEXENO CARBALDEHÍDO, HIDROXICITRONELAL, BUTILFENIL METILPROPIONAL, LIMONENO, LINALOOL.
Caution: For adult use only. Keep out of reach of children. If the product enters the eye, wash out thoroughly with plenty of clean water. Keep powder away from children's nose and mouth. Medical evidence suggests that women who use talcum powder as a feminine hygiene product run a greater risk of developing ovarian cancer.
Mise en garde: Pour adultes seulement. Garder hors de la portée des enfants. Si le produit entre en contact avec les yeux, rincer abondamment à grande eau. Garder la poudre loin du nez et de la bouche des enfants. Les preuves médicales suggèrent fortement que les femmes utilisant la poudre de talc comme produit d'hygiène féminine courent un plus grand risque de développer un cancer de l'ovaire.
Precaución: Solo para uso en adultos. Mantén este producto fuera del alcance de los niños. Si el producto entra en contacto con los ojos, enjuágatelos con abundante agua limpia. Mantén el polvo alejado de la nariz y la boca de los ninõs. La evidencia médica sugiere que las mujeres que usan talco como producto de higiene femenina tienen un riesgo mayor de desarrollar cáncer ovárico.
Belcam Inc., Rouses Point, NY 12979-0277 USA
Imported for / Importé pour / Importado por: Belcam Inc., Candiac, QC J5R 3L5 Canada
Proudly made in U.S.A. Fabriqué avec fierté aux États-Unis Hecho con orgullo en EUA
0 38949 00674 6
12M
www.belcamshop.com
tranquil breeze LB-0067R2


equate™
Compare to Dr. Scholl's® Soothing Foot Powder*
Soothing Foot Powder
• Helps cool feet
• Absorbs excess moisture
• Helps control foot odor
Made in the USA
Factory Certified
NET WT 7 OZ (198 g)


Equate™ Soothing Foot Powder
refreshes your feet.
• Highly absorbent formula helps keep feet dry and comfortable
• Cooling ingredient soothes and refreshes
• Regular use helps control foot odor
Ingredients
Talc, salicylic acid, methyl salicylate
Directions
• Sprinkle generously on all areas of the feet.
• Not intended for genital area.
Warnings
For external use only.
Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.
Other information
• Bottle contains the proper weight.
• Contents may settle during shipping.
Questions?
Call: 1-888-287-1915